British HIV Association
BHIVA

FINAL PROGRAMME

BHIVA Autumn Conference

including

CHIVA Parallel Sessions

17–18 November 2011

Queen Elizabeth II Conference Centre
London

preceded by

Fourth Annual BHIVA Conference for the Management of HIV/Hepatitis Co-infection

1300–1730 Wednesday 16 November 2011
One Great George Street Conference Centre, London

www.bhiva.org

16 CPD Credits
Reference No:
67157

THE CHALLENGE ONLY STARTS AT UNDETECTABLE

In today's HIV landscape, we expect to keep them there, with durable suppression, well-established tolerability and convenient dosing.[1–5] So they can concentrate on dealing with the challenges of life.

ONCE DAILY
REYATAZ®
(atazanavir)
UP TO THE CHALLENGE

REYATAZ® (atazanavir) HARD CAPSULES PRESCRIBING INFORMATION
See summary of product characteristics prior to prescribing

PRESENTATION: Hard capsules: 150mg, 200mg, 300mg atazanavir (as sulphate). **INDICATION:** Antiretroviral combination treatment of HIV-1 infected adults. **DOSAGE AND ADMINISTRATION:** Oral. 300mg with ritonavir 100mg once-daily with food. If coadministered with didanosine, recommend didanosine to be taken two hours after Reyataz with ritonavir with food. **Hepatic impairment:** use with caution in patients with mild hepatic insufficiency. **Renal impairment:** no dosage adjustment required. **CONTRAINDICATIONS:** Hypersensitivity to atazanavir or any excipient. Moderate to severe hepatic insufficiency. Do not use in combination with rifampicin or products that are substrates of CYP3A4 and have a narrow therapeutic windows or products containing St. John's wort. Reyataz with ritonavir is contraindicated in patients undergoing haemodialysis. DPE5 inhibitor sildenafil is contraindicated when used for the treatment of pulmonary arterial hypertension (PAH) only. **SPECIAL WARNINGS AND PRECAUTIONS:** Patients with chronic hepatitis B or C treated with combination antiretroviral therapy are at increased risk of severe and potentially fatal hepatic adverse events. Patients with pre-existing liver dysfunction must be monitored according to practice. In worsening liver disease consider interruption or discontinuation of treatment. Patients should be monitored for Stevens-Johnson syndrome (SJS) erythema multiforme, toxin skin eruptions and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome which have been reported. Reyataz should be discontinued if severe rash develops. Reyataz may induce PR prolongations. Caution with medicines that may increase QT interval. Caution in haemophiliac patients. Combination antiretroviral therapy has been associated with lipodystrophy and metabolic abnormalities. Particular caution is required when prescribing PDE5-inhibitors (sildenafil, tadalafil, or vardenafil) for the treatment of erectile dysfunction in patients receiving Reyataz with concomitant low dose of ritonavir. Co-administration of salmeterol and Reyataz is not recommended. In clinical studies, Reyataz (with or without ritonavir) has been shown to induce dyslipidemia to a lesser extent than comparators. Hyperbilirubinaemia has occurred in patients receiving Reyataz; no dose reduction is recommended. Nephrolithiasis has been reported in patients receiving Reyataz. If signs or symptoms occur, temporary interruption or discontinuation of treatment may be considered. On initiation of combination therapy immune reactivation syndrome may occur. **DRUG INTERACTIONS:** Coadministration of REYATAZ with the following agents is not recommended: simvastatin, lovastatin, nevirapine efavirenz, proton pump inhibitors or tenofovir & an H2-receptor antagonist. **Oral contraceptives:** *ethinyloestradiol 25µg & norgestimate coadministered with atazanavir 300mg with ritonavir 100 mg QD:* recommended minimum 30 µg ethinyloestradiol. Remind patient of strict compliance with dosing regimen. Co-administration with other hormonal or oral contraceptives has not been studied - therefore avoid. Alternate reliable methods of contraception recommended. Coadministration of Reyataz/ ritonavir is not recommended for the following unless justified by the benefit/risk ratio; voriconazole fluticasone or other glucocorticoids that are metabolised by CYP3A4. **PREGNANCY AND LACTATION:** Avoid use in pregnancy and lactation. **UNDESIRABLE EFFECTS:** *Common:* nausea, headache, ocular icterus, vomiting, diarrhoea, dyspepsia, abdominal pain, jaundice, rash, fatigue and lipodystrophy *Uncommon:* insomnia, asthenia, pancreatitis, peripheral neurologic symptoms, hepatitis, nephrolithiasis, erythemia multiforme, toxic skin eruptions, drug rash with eosinophilia and systemic symptoms (DRESS) syndrome, *Rare:* Stevens-Johnson syndrome. *Rare:* myopathy,. Consult SPC for other side effects. **LABORATORY ABNORMALITIES** Elevated bilirubin, creatinine kinase **LEGAL STATUS:** POM. **PACKAGE QUANTITIES AND BASIC NHS PRICE:** Carton of 60 hard capsules, 150mg: £303.38, 200mg: £303.38, carton of 30 capsules, 300mg: £303.38 **MARKETING AUTHORISATION NUMBERS:** EU/1/03/267/003 - 150mg Bottle; EU/1/03/267/005 - 200mg Bottle. EU/1/03/267/008 -300mg Bottle **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, BMS House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex. UB8 1DH. Telephone: 0800-731-1736. **DATE OF PI PREPARATION:** September 2011 687UK11PM058

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Bristol-Myers Squibb Pharmaceuticals Ltd Medical Information on 0800 731 1736, medical.information@bms.com

References
1. Daar ES *et al. Ann Intern Med.* 2011;154(7):445–456. 2. Molina JM and the CASTLE Study Team. *J Acquir Immune Defic Syndr.* 2010;53(3):323–332. 3. Jansen K *et al.* and Competence Network for HIV/AIDS. HIV10, Glasgow, UK. Poster P031. 4. Maggiolo F *et al.* IAC 2010. Poster TUPE0178. 5. REYATAZ® (atazanavir) Summary of Product Characteristics SmPC August 2011, http://emc.medicines.org.uk. Accessed September 2011.

Bristol-Myers Squibb

Date of preparation: July 2011 687EMEA11PM047
UKRZ-K0007

INTRODUCTION

Publication date: October 2011

CONTENTS

Dear Colleague

Welcome to the BHIVA Autumn Conference in 2011 which, once again, is held at the **Queen Elizabeth II Conference Centre**. Located in the heart of London, the centre provides all the facilities required for our delegates. I would like to thank Ed Wilkins (Chair of the Conference Subcommittee), Mark Nelson (Conference Local Host) and all the members of the Conference Subcommittee for their efforts in preparing an excellent programme for this conference.

This year our Autumn Conference is preceded by the Fourth Annual Conference for the Management of HIV/Hepatitis Co-infection held at **One Great George Street Conference Centre** immediately adjacent to the QEII Conference Centre.

The BHIVA plenary programme will cover a wide range of important topics relevant to HIV. Please refer to the programme pages for a full schedule of topics and timings. We are particularly delighted to welcome a number of eminent speakers to London and our international speakers include **Dr Rachel Baggaley**, **Dr Pierre Corbeau**, **Professor Bob Grant**, **Professor Barbara McGovern** and **Dr Andri Rauch**.

The BHIVA Annual General Meeting will be held on Friday 18 November prior to lunch. I would encourage all BHIVA members to attend this meeting as it provides a forum to present any points they may have to the Officers and members of the Executive Committee.

Finally, we would like to thank our sponsors for their continued support of the Association which assists greatly with covering some of the costs incurred in organising this conference.

We very much hope you will enjoy the conference and find it relevant to both your educational and practical needs.

Professor Jane Anderson
Chair, British HIV Association

VENUES

BHIVA HIV/Hepatitis Conference	*One Great George Street Conference Centre, London SW1P 3AA*
Lecture Theatre	*Godfrey Mitchell Theatre, Lower Ground Floor*
Exhibition and Catering	*Council Room, Ground Floor*
BHIVA Autumn Conference	*QEII Conference Centre, Broad Sanctuary, London SW1P 3EE*
Registration	*Sanctuary Foyer, Ground Floor*
Lecture Theatre (all BHIVA sessions)	*Fleming Room, Third Floor*
Lunchtime Workshops	*Abbey Room & Henry Moore Room Fourth Floor*
Satellite Symposia	*Fleming Room, Third Floor*
Exhibition	*Benjamin Britten Lounge, Third Floor*
Lunch and Refreshments	*Benjamin Britten Lounge, Third Floor*
Speakers' Presentation Preview Room	*East Long Room, Third Floor*
Drinks Reception	*Benjamin Britten Lounge, Third Floor*
CHIVA Parallel Sessions	*QEII Conference Centre, Broad Sanctuary, London SW1P 3EE*
Lecture Theatre	*Westminster Suite, Fourth Floor*

16 CPD Credits Unique reference number: **67157**

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BHIVA COMMITTEES

EXECUTIVE COMMITTEE

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Homerton University Hospital, London

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Cardiff University School of Medicine

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University College London Medical School

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St Thomas' Hospital, London

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Chelsea and Westminster Hospital, London

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Royal Victoria Infirmary, Newcastle

Dr AJ Palfreeman
Leicester Royal Infirmary

Ms S Petretti
UK Community Advisory Board

Dr EGL Wilkins
North Manchester General Hospital

HEPATITIS WORKING GROUP (BHWG)

EXECUTIVE PANEL

Dr Kosh Agarwal
Invited Representative

Dr Sanjay Bhagani
BHIVA Executive Committee member

Dr Gary Brook
Invited Representative

Mr Robert James
Patient Representative

Dr Ranjababu Kulasegaram
Vice Chair

Prof Clifford Leen
BHIVA Executive Committee member

Dr Mark Nelson
Chair

Dr Ed Wilkins
BHIVA Executive Committee member

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BHIVA Executive Committee member

Dr David Asboe
BHIVA Honorary Treasurer

Prof Mark Bower
BHIVA Executive Committee member

Dr David Chadwick
Invited Representative

Dr Satyajit Das
BHIVA Executive Committee member/
Local Host, Birmingham 2012

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Dr Ranjababu Kulasegaram
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Prof Sebastian Lucas
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Local Host, Autumn 2011

Dr Chloe Orkin
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Dr Adrian Palfreeman
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Ms Silvia Petretti
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Dr Ed Wilkins
Chair

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PROGRAMME SUMMARY

WEDNESDAY 16 NOVEMBER

Fourth Annual BHIVA Conference for the Management of HIV/Hepatitis Co-infection

1300–1600	Registration and exhibition open
1300–1350	Lunch
1350–1400	Welcome Address
1400–1530	Plenary Session 1
1530–1600	Afternoon tea
1600–1730	Plenary Session 2
1730	Summary and close

THURSDAY 17 NOVEMBER

BHIVA Autumn Conference

0815–1830	Registration and exhibition open
0855–0900	Welcome Address
0900–1000	BHIVA Symposium
1000–1030	Brian Gazzard Lectureship in HIV Medicine
1030–1100	Morning coffee
1100–1200	BHIVA Guidelines Session
1200–1230	BHIVA Foundation Lecture
1230–1400	Lunch
1240–1325	BHIVA Lunchtime Workshop 1
1255–1355	Bristol-Myers Squibb Pharmaceuticals Lunchtime Workshop
1400–1500	BHIVA Plenary Session 1
1500–1515	BHIVA Audit Session
1515–1530	Launch of the standards for psychological support for adults living with HIV
1530–1600	BHIVA Invited Lecture 1
1600–1630	Afternoon tea
1630–1730	BHIVA Community Symposium
1730–1830	Gilead Sciences Satellite Symposium
1830–1930	Drinks Reception

FRIDAY 18 NOVEMBER

	BHIVA Autumn Conference	CHIVA Parallel Sessions
0815–1630	Registration and exhibition open	
0900–1000	Abbott Satellite Symposium	Parallel Session 1
1000–1030	BHIVA Invited Lecture 2	
1030–1100	Morning coffee	
1100–1230	BHIVA Plenary Session 2	Parallel Session 2
1230–1300	CHIVA Plenary Lecture	
1300–1320	BHIVA Annual General Meeting	
1300–1430	Lunch	
1325–1410	BHIVA Lunchtime Workshop 2	
1325–1425	Janssen Lunchtime Workshop	CHIVA EGM
1430–1500	BHIVA Invited Lecture 3	Parallel Session 3
1500–1600	Bristol-Myers Squibb Pharmaceuticals Satellite Symposium	
1600–1700	BHIVA Plenary Session 3	
1700	Close	

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PROGRAMME

WEDNESDAY 16 NOVEMBER

British HIV Association BHIVA

FOURTH ANNUAL BHIVA CONFERENCE FOR THE MANAGEMENT OF HIV/HEPATITIS CO-INFECTION

◄ All sessions will be held in the Godfrey Mitchell Theatre at One Great George Street Conference Centre ►

1300–1600	Registration and exhibition open at One Great George Street Conference Centre
1300–1350	Lunch
1350–1400	**Welcome Address** *by the Chair of the BHIVA Hepatitis Working Group* Dr Mark Nelson *Chelsea and Westminster Hospital, London*
1400–1530	**Plenary Session 1** Chair: Mr Robert James *The National Birchgrove Group* **Didanosine and the liver: diagnosis, monitoring and treatment of non-cirrhotic portal hypertension** Dr Sanjay Bhagani *Royal Free Hospital, London* **IL28b and other new predictors of success** Dr Andri Rauch *University Hospital of Bern, Switzerland*
1530–1600	Afternoon tea
1600–1700	**Plenary Session 2** Chair: Dr Ranjababu Kulasegaram *St Thomas' Hospital, London* **New drugs for hepatitis C in the HIV co-infected** Professor Geoff Dusheiko *Royal Free Hospital, London* **When will we have an interferon-sparing approach to hepatitis?** Dr Kosh Agarwal *King's College, London*
1700–1730	**Panel discussion**
1730	**Summary and close** Dr Mark Nelson *Chelsea and Westminster Hospital, London*

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PROGRAMME

THURSDAY 17 NOVEMBER

British HIV Association BHIVA

BHIVA AUTUMN CONFERENCE

◄ All sessions will be held in the Fleming Room, Third Floor, QEII Conference Centre unless otherwise stated ►

0815–1830	Registration and exhibition open at the QEII Conference Centre

0855–0900 **Welcome Address** *by the Chair of the British HIV Association*

Professor Jane Anderson
Homerton University Hospital, London

0900–1000 **BHIVA Symposium: HIV/hepatitis co-infection**

Chairs: Dr Gary Brook
Central Middlesex Hospital, London
Dr Ed Wilkins
North Manchester General Hospital

Where have we come from?

Professor Barbara McGovern
Tufts University School of Medicine, Boston, USA

Where are we going?

Professor Geoff Dusheiko
Royal Free Hospital, London

BHIVA is grateful for an educational grant in support of this symposium from MSD Ltd

1000–1030 **Brian Gazzard Lectureship in HIV Medicine**

Chair: Professor Brian Gazzard
Chelsea and Westminster Hospital, London

Gender, genomes and antiretroviral hypersensitivity

Dr Mas Chaponda
University of Liverpool

1030–1100 Morning coffee

1100–1200 **BHIVA Guidelines Session**

Chairs: Dr Martin Fisher
Royal Sussex County Hospital, Brighton
Dr Adrian Palfreeman
Leicester Royal Infirmary

Treatment of HIV-1-infected adults with antiretroviral therapy

Dr Ian Williams
University College London Medical School

Management of HIV infection in pregnant women

Dr Annemiek de Ruiter
St Thomas' Hospital, London

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1200–1230 **BHIVA Foundation Lecture**

Chair: Professor Jane Anderson
Homerton University Hospital, London

The impact of the global recession on HIV and AIDS

Professor Tony Barnett
London School of Economics

1230–1400 Lunch and Lunchtime Workshops

1240–1325 **BHIVA Interactive Lunchtime Workshop 1** Abbey Room, Fourth Floor
(Lunchpacks will be provided: see page 16 for further details)

Clinico-pathological SpR case presentations

Chair: Professor Sebastian Lucas
St Thomas' Hospital, London

HIV brain pathology was never easy: two challenging biopsy cases

Dr Mitesh Desai
Guy's and St Thomas' NHS Foundation Trust, London

Dr Lavanya Raman
Chelsea and Westminster Hospital, London

1255–1355 **Bristol Myers-Squibb Pharmaceuticals Lunchtime Workshop**
Henry Moore Room, Fourth Floor
(see page 14 for further details)

1400–1500 **BHIVA Plenary Session 1**

Chairs: Dr Duncan Churchill
Royal Sussex County Hospital, Brighton
Dr Simon Edwards
University College London Medical School

Which viral characteristics matter?

Professor Deenan Pillay
University College London

The importance of ultra-deep sequencing in clinical practice

Dr Erasmus Smit
Birmingham Heartlands Hospital

1500–1515 **BHIVA Audit Session**

Chair: Professor Jane Anderson
Homerton University Hospital, London

HQIP and future topics

Dr Ed Ong
Royal Victoria Infirmary, Newcastle

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1515–1530 **Launch of the standards for psychological support for adults living with HIV**

Chair: Professor Jane Anderson
Homerton University Hospital, London

Dr Liz Shaw
Barnet, Enfield and Haringey Mental Health Trust, London

1530–1600 **BHIVA Invited Lecture 1**

Chair: Dr David Asboe
Chelsea and Westminster Hospital, London

The importance of immune activation

Dr Pierre Corbeau
University of Montpellier, France

1600–1630 Afternoon tea

1630–1730 **BHIVA Community Symposium**

New trends in prevention and Greater Involvement of People with HIV/AIDS (GIPA)

Chairs: Dr Carol Emerson
The Royal Hospitals, Belfast

Ms Silvia Petretti
Positively UK

A synthesis of PrEP studies

Professor Bob Grant
University of California San Francisco, USA

The individual: making the right choice

Mr Gus Cairns
NAM

Ms Eunice Sinyemu
African Health Policy Network

Panel discussion

1730–1830 **Gilead Sciences Satellite Symposium**
(see page 14 for further details)

1830–1930 **Drinks Reception**
Benjamin Britten Lounge, QEII Conference Centre

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PROGRAMME

FRIDAY 18 NOVEMBER

British HIV Association BHIVA

BHIVA AUTUMN CONFERENCE

◄ All sessions will be held in the Fleming Room, Third Floor, QEII Conference Centre unless otherwise stated ►

0815–1430	Registration and exhibition open at the QEII Conference Centre
0900–1000	**Abbott Satellite Symposium** (see page 14 for further details)
1000–1030	**BHIVA Invited Lecture 2** Chair: Professor Mark Bower *Chelsea and Westminster Hospital, London* **HIV vaccines: lessons learnt and future promise** Professor Andrew McMichael *University of Oxford*
1030–1100	Morning coffee
1100–1230	**BHIVA Plenary Session 2** **Best Practice Management Session** Chairs: Dr Sanjay Bhagani *Royal Free Hospital, London* Dr Andrew Freedman *Cardiff University School of Medicine* **When to start antiretrovirals: tuberculosis and cryptococcal infection** Dr Anton Pozniak *Chelsea and Westminster Hospital, London* **Fat accumulation: causes and management** Dr Graeme Moyle *Chelsea and Westminster Hospital, London* **Management of serodiscordant couples** Dr Yvonne Gilleece *Royal Sussex County Hospital, Brighton*
1230–1300	**CHIVA Plenary Lecture** Chair: Dr Steve Welch *Birmingham Heartlands Hospital* **Disclosure and HIV: an international perspective** Dr Rachel Baggaley *World Health Organization*
1300–1320	**BHIVA Annual General Meeting**
1300–1430	Lunch and Lunchtime Workshops

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1325–1410 **BHIVA Lunchtime Workshop 2** Abbey Room, Fourth Floor
(Lunchpacks will be provided: see page 16 for further details)

HIV and the kidneys

Dr Frank Post
King's College London

Dr Rachael Jones
Chelsea and Westminster Hospital, London

1325–1425 **Janssen Lunchtime Workshop** Henry Moore Room, Fourth Floor
(see page 14 for further details)

1430–1500 **BHIVA Invited Lecture 3**

Chair: Dr Ranjababu Kulasegaram
St Thomas' Hospital, London

Acute hepatitis C

Dr Emma Page
Chelsea and Westminster Hospital, London

1500–1600 **Bristol-Myers Squibb Pharmaceuticals Satellite Symposium**
(see page 14 for further details)

1600–1700 **BHIVA Plenary Session 3**

A rare opportunity: three past BHIVA Chairs – clinical conundrums

Chair: Professor Clifford Leen
Western General Hospital, Edinburgh

Clinical conundrums

Dr Mark Nelson
Chelsea and Westminster Hospital, London

Expert Panel

Professor Brian Gazzard
Chelsea and Westminster Hospital, London

Professor Margaret Johnson
Royal Free Hospital, London

Dr Ian Williams
University College London Medical School

1700 **Close** *by the Chair of the British HIV Association*

Professor Jane Anderson
Homerton University Hospital, London

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PROGRAMME

FRIDAY 18 NOVEMBER

Please read the CHIVA Parallel Sessions programme in conjunction with the BHIVA Autumn Conference programme

CHILDREN'S chiva HIV ASSOCIATION

CHIVA PARALLEL SESSIONS

DISCLOSURE AND PEER SUPPORT

◄ Parallel sessions will be held in the Westminster Suite, Fourth Floor, QEII Conference Centre, unless otherwise stated ►

0855–0900 **Welcome** *by the Chair of the Children's HIV Association and the Conference Local Host*

Dr Steve Welch
Birmingham Heartlands Hospital

Mrs Diane Melvin
Imperial College Healthcare NHS Trust, London

Parallel Session 1: Disclosure revisited

Chair: Dr Toni Tan
North Manchester General Hospital

0900–0930 **What have we learnt about disclosure and HIV for children in the UK?**
Mrs Diane Melvin
Imperial College Healthcare NHS Trust, London

0930–0950 **Young people: who to tell and how to safely share knowledge**
Ms Emily Hamblin
National Children's Bureau

0950–1030 **CHIVA Debate**

Chair: Dr Colin Ball
King's College Hospital, London

The motion

This house believes it is in the interest of the young person that the disclosure of the HIV diagnosis be universal to education and to GPs

For the motion: Mrs Jude Ragan
Queensmill Primary School, London

Dr Nina Pearson
Lea Vale Medical Group, Luton

Against the motion: Mr Djamel Hamadache
Chelsea and Westminster Hospital, London

1030–1100 *Morning coffee*
Benjamin Britten Lounge, Third Floor

Parallel Session 2

Chair: Dr Ali Judd
MRC Clinical Trials Unit, London

1100–1130 **Commissioning update**
Mrs Claire Foreman
London Specialised Commissioning Group

1130–1150 **Audit update: vitamin D**
Dr Ed Clarke
Bristol Royal Hospital for Children

1150–1220 **Neuro-cognitive function in adolescents**
Dr Caroline Foster
Imperial College Healthcare NHS Trust, London

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1230–1300 **CHIVA Plenary Lecture**
Fleming Room, Third Floor (see page 10 for further details)

1300–1320 **BHIVA Annual General Meeting**
Fleming Room, Third Floor

1300–1430 *Lunch*
Benjamin Britten Lounge and Whittle Room, Third Floor

1410–1430 **CHIVA Extraordinary General Meeting** *(CHIVA members only)*

1430–1530 **CHIVA Regional Networks Update**

Chair: Dr Fiona Thompson
Northampton General Hospital

Midlands:	Dr Lucy Cliffe *Nottingham University Hospitals NHS Trust*	
North East England:	Ms Marie Dowie *Leeds General Infirmary*	Mr Paul Box *Leeds Skyline Service*
North West England:	Dr Andrew Riordan *Alder Hey Children's NHS Foundation Trust, Liverpool*	Ms Jill Hellings *Barnardo's*
Scotland:	Dr Conor Doherty *Royal Hospital for Sick Children, Glasgow*	Ms Lynne Williamson *Waverley Care*
South West England & Wales:	Ms Katrina Humphreys *Southampton City Primary Care Trust*	Ms Jan Wallis *Groundswell*
South East England:	Dr Amanda Williams *CHIVA Honorary Secretary*	

Parallel Session 3

Chairs: Ms Maren Koros
Portsmouth Hospitals NHS Trust
Dr Amanda Williams
CHIVA Honorary Secretary

1530–1600 **Interventions for serodiscordant couples**
Dr Rachel Baggaley
World Health Organization

1600–1620 **Obesity and HIV: dyslipidemia in young people**
Ms Julie Lanigan
Institute of Child Health, London

1620–1630 **CHIVA Projects update**

1630–1700 **Antiretroviral update**
Dr Steve Taylor
Birmingham Heartlands Hospital

1700 **Close** *by the Chair of the Children's HIV Association*
Dr Steve Welch
Birmingham Heartlands Hospital

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PROGRAMME OF SATELLITE SYMPOSIA AND SPONSORS' LUNCHTIME WORKSHOPS

All satellite symposia will be held in the **Fleming Room**, **Third Floor**, QEII Conference Centre
Locations of sponsors' workshops are listed below adjacent to the respective events

THURSDAY 17 NOVEMBER

1255–1355

Bristol-Myers Squibb Pharmaceuticals Lunchtime Workshop Debate
(Henry Moore Room, Fourth Floor)
Registration will be administered at the door on a first-come, first-served basis

ART as a prevention measure will have a major impact on the UK HIV epidemic

Chair: Dr Sarah Fidler
Imperial College School of Medicine at St Mary's Hospital, London

Professor Brian Gazzard
Chelsea and Westminster Hospital, London

Dr Martin Fisher
Royal Sussex County Hospital, Brighton

1730–1830

Gilead Sciences Satellite Symposium

What lessons can we learn from the Developing World?

Chair: Dr Mark Nelson
Chelsea and Westminster Hospital, London

Dr Charles Mazhude
University Hospital Lewisham, London

Dr Jim Rooney
Gilead Sciences USA

Mr Clifford Samuel
Gilead Sciences USA

FRIDAY 18 NOVEMBER

0900–1000

Abbott Satellite Symposium

Women with HIV: A new age – a new generation

From menarche to menopause

Dr Carol Emerson
The Royal Hospitals, Belfast

A new age in HIV: clinical challenges of extending life spans

Professor Margaret Johnson
Royal Free Hospital, London

1325–1425

Janssen Lunchtime Workshop *(Henry Moore Room, Fourth Floor)*
Pre-registration is required and tickets will be collected at the door

Practicalities with the proteases:
DAAs in the co-infected and mono-infected patient, the MDT approach

Chair: Dr Mark Nelson
Chelsea and Westminster Hospital, London

Dr Kosh Agarwal
King's College Hospital, London

Ms Sarah Knighton
King's College Hospital, London

Ms Jo Schulz
Barts and The London School of Medicine

1500–1600

Bristol-Myers Squibb Pharmaceuticals Satellite Symposium

Seminal research in HIV and future perspectives for research and drug development

Chair: Dr Ed Wilkins
North Manchester General Hospital

Professor Brian Gazzard
Chelsea and Westminster Hospital, London

Dr Graeme Moyle
Chelsea and Westminster Hospital, London

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CONFERENCE INFORMATION

Registration

Your registration fee includes access to the scientific sessions as indicated below for each meeting, including satellite symposia and exhibition stands.

BHIVA Autumn Conference: 17–18 November 2011

The registration fee gives access to the scientific sessions of the BHIVA Autumn Conference and the CHIVA Parallel Sessions, including satellite symposia. All refreshments and lunches throughout the conference are included in the registration fee.

BHIVA Lunchtime Workshops

Places are limited and will be restricted to 80 delegates per workshop. Places will be available on site, on a first-come, first-served basis, at the door of the lunchtime workshop. Doors will open 15 minutes prior to the start of each workshop. Each workshop will begin promptly and lunchpacks will be provided for delegates attending these sessions.

Fourth Annual BHIVA Conference for the Management of HIV/Hepatitis Co-infection: 1300–1730 Wednesday 16 November 2011

The registration fee gives access to the Fourth Annual BHIVA Conference for the Management of HIV/Hepatitis Co-infection on Wednesday afternoon at One Great George Street Conference Centre, prior to the BHIVA Autumn Conference. Lunch and afternoon refreshments are included in the registration fee. Please note that places are limited to a maximum of 100 delegates and have been allocated, in principle, on a first-come, first-served basis. All applicants will have been informed before conference whether or not their registration has been successful.

Children's HIV Association (CHIVA) Parallel Sessions: 0900–1700, Friday 18 November 2011

The registration fee gives access to the CHIVA Parallel Sessions and the CHIVA Plenary Session. In addition, refreshments and lunch on Friday 18 November are included. The Parallel Sessions are preceded by the CHIVA Dinner at a central London location from 2000 on Thursday 17 November for those who have booked tickets and paid the necessary fee.

Drinks Reception

The Drinks Reception immediately follows the conference programme at 1830–1930 on Thursday 17 November and will take place in the exhibition area located in the Benjamin Britten Lounge on the Third Floor.

BHIVA Community Registration

BHIVA has supported free registration for over 40 community representatives to attend the conference.

BHIVA Registration Scholarships

BHIVA Registration Scholarships have been made available to 20 delegates who are doctors and who are retired, not working or employed in a part-time or equivalent capacity, or who are students involved in full-time undergraduate or post-graduate work. The scholarships cover the conference registration fee.

Continuing Professional Development (CPD)

Medical staff in career grade posts who are enrolled with one of the Royal Medical Colleges for Continuing Professional Development will receive CPD credit at the rate of one CPD credit per conference hour (exclusive of travel, refreshments, social events and satellite symposia). The conference will be allocated a maximum of 6 CPD credits per conference day.

CPD Accreditation: Credits attributed & unique reference number		
Fourth Annual BHIVA Conference for the Management of HIV/Hepatitis Co-infection	**4** Credits	67157
BHIVA Autumn Conference including CHIVA Parallel Sessions	**12** Credits	67157
CHIVA Parallel Sessions *only*	**6** Credits	67157

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NEW
VICTRELIS®
boceprevir

NOW AVAILABLE

Victrelis is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy.[1]

Prescribing Information can be found on the reverse of this page.

MSD

®

Reference:
1. Victrelis Summary of Product Characteristics

07-12 VIC.11.GB.118611.J

Date of preparation: July 2011

Printed in England

VICTRELIS®▼ (boceprevir)
ABRIDGED PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to MSD (01992-467272).

PRESENTATION: 200mg hard capsule each containing 200 mg of boceprevir. **USES:** Victrelis is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin (PR), in adult patients with compensated liver disease who are previously untreated or who have failed previous therapy. **DOSAGE AND ADMINISTRATION:** Treatment with Victrelis should be initiated and monitored by a physician experienced in the management of CHC. Victrelis must be administered in combination with peginterferon alfa and ribavirin (PR). Consult the Summary of Product Characteristics (SmPC) of peginterferon alfa and ribavirin prior to initiation of therapy with Victrelis. Adults: 800 mg orally TID with food). Maximum daily dose: 2,400 mg. Administration without food could be associated with a net loss of efficacy due to sub-optimal exposure. *Patients without cirrhosis who are previously untreated or who have failed previous therapy* These dosing recommendations differ for some subgroups from the dosing studied in the Phase 3 trials.

	ASSESSMENT* (HCV-RNA Results†)		ACTION
	At Treatment Week 8	At Treatment Week 24	
Previously Untreated Patients	Undetectable	Undetectable	*Treatment duration = 28 weeks* 1. Give PR for 4 weeks, and then 2. Continue with all 3 ([PR] + Victrelis) and finish through Treatment Week 28 (TW 28).
	Detectable	Undetectable	*Treatment duration = 48 weeks* 1. Give PR for 4 weeks, and then 2. Continue with all 3 (PR + Victrelis) and finish through TW 36; and then 3. Give PR and finish through TW 48.
Patients Who have Failed Previous Therapy	Undetectable	Undetectable	*Treatment duration = 48 weeks* 1. Give PR for 4 weeks, and then 2. Continue with all 3 (PR + Victrelis) and finish through TW 36, and then 3. Give PR and finish through TW 48.
	Detectable	Undetectable	

***Stopping rule**
If patient has HCV-RNA results ≥ 100 IU/ml at TW 12; then discontinue 3-medicine regimen.
If the patient has confirmed, detectable HCV-RNA at TW 24; discontinue 3-medicine regimen.
PR – Peginterferon alfa and ribavirin

07-12 VIC.11.GB.118611.J

All cirrhotic patients and null responders: Recommended treatment duration is 48 weeks: 4 weeks of dual therapy with peginterferon alfa and ribavirin + 44 weeks of triple therapy with peginterferon alfa, ribavirin +Victrelis. (Refer to the stopping rule in Table 1 for all patients.)Duration of the triple therapy after the first 4 weeks of dual therapy should not be less than 32 weeks. Given the incremental risk of adverse events with Victrelis (anaemia notably); if the patient cannot tolerate triple therapy consider dual therapy of peginterferon alfa + ribavirin for the final 12 weeks of treatment instead. *Missed doses:* If the missed dose is less than 2 hours before next dose is due, the missed dose should be skipped. If a dose is missed 2 or more hours before the next dose is due, take the missed dose with food and resume the normal dosing schedule. *Dose reduction:* Not recommended. In case of serious adverse reactions potentially related to peginterferon alfa and/or ribavirin, the peginterferon alfa and/or ribavirin, dose should be reduced. Refer to the individual SmPC for information about how to reduce and/or discontinue the peginterferon alfa and/or ribavirin dose. Do not give Victrelis monotherapy. Renal impairment: No dose adjustment needed with any degree of impairment. Hepatic impairment: No dose adjustment needed No data in patients with decompensated cirrhosis. *Paediatric population:* No data available. Elderly: Insufficient numbers in clinical studies to determine whether they respond differently to younger subjects. **CONTRA-INDICATIONS:** Hypersensitivity to the active substance or any of the excipients. Autoimmune hepatitis; Co-administration with medicines highly dependent on CYP3A4/5 for clearance, and for which elevated plasma concentrations are associated with serious and/or life-threatening events such as orally administered midazolam and triazolam, bepridil, pimozide, lumefantrine, halofantrine, tyrosine kinase inhibitors, and ergot derivatives (dihydroergotamine, ergonovine, ergotamine, methylergonovine); Pregnancy. **PRECAUTIONS:** Anaemia: Onset of anaemia has been reported with peginterferon alfa + ribavirin therapy by TW 4. The addition of Victrelis to PR is associated with an additional decrease in haemoglobin concentrations of approx 1 g/dl by TW 8 compared to standard of care. Obtain full blood counts pretreatment, TW 4, TW 8, and thereafter, as appropriate. If Haemoglobin is < 10 g/dl (or < 6.2 mmol/l) consider anaemia management. Neutropenia: Addition of Victrelis to peginterferon alfa + ribavirin resulted in higher incidences of neutropenia and Grade 3-4 neutropenia compared with PR alone. Frequency of severe or life threatening infections tends to be higher in Victrelis-containing arms than the control arm. Evaluate neutrophils counts before and regularly after treatment starts. Evaluate and treat infections promptly. *Combined use with peginterferon alfa–2a as compared to alfa–2b:* Compared to the combination of Victrelis with peginterferon alfa–2b and ribavirin, the combination of Victrelis with peginterferon alfa–2a and ribavirin was associated with a higher rate of neutropenia (including grade 4 neutropenia) and a higher rate of infections. Use in prior null responders: Null responders might gain some benefit in adding Victrelis to peginterferon alfa and ribavirin. Optimal management of null responders remains to be established. Contains lactose: Not for use in rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Proarrhythmic effects: Use caution in patients at risk of QT prolongation (long congenital QT, hypokalaemia). Use in patients with HIV co-infection : Safety and efficacy has not been established. A clinical study is ongoing. Use in patients with HBV co-infection/organ transplant: Has not been studied. Use in patients having HCV genotypes other than G1: Safety and efficacy has not been established. Use in patients who have previously failed treatment with an HCV protease inhibitor: Has not been studied. **Drug Interactions:** Victrelis is a strong inhibitor of CYP3A4/5. Medicines metabolized primarily by CYP3A4/5 may have increased exposure when administered with Victrelis, which may increase or prolong therapeutic and adverse reactions. It does not inhibit or induce the other enzymes of the CYP450. Victrelis is partly metabolized by CYP3A4/5. Co-administration with medicines that induce or inhibit CYP3A4/5 could increase or decrease exposure to Victrelis. Use with rifampicin or anticonvulsants (eg phenytoin, phenobarbital or carbamazepine) may significantly reduce the plasma exposure of Victrelis and is not-recommended). Exercise caution with medicines known to prolong QT interval such as amiodarone, quinidine, methadone, pentamidine and some neuroleptics. **Pharmacokinetic interactions:** *Ketoconazole or azole antifungals:* exercise caution; *Ritonavir:* No data are currently available with ritonavir as a booster in combination with protease inhibitors. Theoretically, the combination of Victrelis with PIs/ritonavir is not expected to result in clinically significant interactions; Efavirenz: plasma trough concentrations of Victrelis were decreased. The clinical outcome has not been directly assessed; Raltegravir: no data but pay attention; *Drospirenone/Ethinyl estradiol:* exercise caution in patients predisposed to hyperkalaemia or taking K+sparing diuretics; Use alternative OCs. *Midazolam/triazolam (oral administration):* contraindicated; *IV benzodiazepines:* monitor closely. *Immunosuppressants:* Therapeutic medicine monitoring is recommended when administering Victrelis with CYP3A4/5 substrates that have a narrow therapeutic window (e.g, tacrolimus, ciclosporin). Individual patients may require a change in their immunosuppressant dosage when Victrelis is started or stopped to ensure clinically effective blood levels; *Statins:* Individual patients may require a change in statin dosage when Victrelis is started or stopped to ensure clinically effective blood levels; *Methadone:* Individual patients may require a change in methadone dosage when Victrelis is started or stopped to ensure clinically effective blood levels. Pregnancy: Contraindicated patients and partners must use two effective forms of contraception during treatment. Breastfeeding: A risk to the newborns/infants cannot be excluded. Make decision considering the benefit of breastfeeding for the child and the benefit of therapy for the woman. **SIDE EFFECTS: Refer to Summary of Product Characteristics for complete information on side-effects.** Most frequently reported adverse reactions were fatigue, anaemia, nausea, headache, and dysgeusia. Most common reason for dose reduction was anaemia, which occurred more frequently in subjects receiving the combination of Victrelis with peginterferon alfa and ribavirin than in subjects receiving peginterferon alfa 2b and ribavirin alone. Adverse Reactions are listed under headings of frequency using the categories: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000). *Very common:* Anaemia, neutropenia, decreased appetite, anxiety, depression, insomnia, irritability, dizziness, headache, cough, dyspnoea, diarrhoea, nausea, vomiting dry mouth, dysgeusia, alopecia, dry skin, pruritus, rash, arthralgia, myalgia, asthenia, chills, fatigue, pyrexia, influenza-like illness, weight decreased. *Common:* Bronchitis, cellulitis, herpes simplex, influenza, oral fungal infection, sinusitis, leukopenia, thrombocytopenia, goitre, hypothyroidism, dehydration, hyperglycaemia, hypertriglyceridaemia, hyperuricaemia, affect lability, agitation, libido disorder, mood altered, sleep disorder, hypoaesthesia, paraesthesia, syncope, amnesia, disturbance in attention, memory impairment, migraine, parosmia, tremour, vertigo, dry eye, retinal exudates, vision blurred, visual impairment, tinnitus, palpitations, hypotension, hypertension, epistaxis, nasal congestion, oropharyngeal pain, respiratory tract congestion, sinus congestion, wheezing, abdominal pain, abdominal pain upper, constipation, gastrooesophageal reflux disease, haemorrhoids, abdominal discomfort, abdominal distention, anorectal discomfort, aphthous stomatitis, cheilitis, dyspepsia, flatulence, glossodynia, mouth ulceration, oral pain, stomatitis, tooth disorder, dermatitis, eczema, erythema, hyperhidrosis, night sweats, oedema peripheral, psoriasis, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic, skin lesion, back pain, pain in extremity, muscle spasms, muscular weakness, neck pain, pollakiuria, erectile dysfunction, chest discomfort, chest pain, malaise, feeling of body temperature change, mucosal dryness, pain. *Uncommon serious:* Pneumonia haemorrhagic diathesis, lymphopenia, hyperthyroidism, hypokalaemia diabetes mellitus, suicidal ideation, confusional state, loss of consciousness, retinal ischaemia, retinopathy, deep vein thrombosis, pulmonary embolism, dry pancreatitis, rectal haemorrhage. *Rare serious:* Epiglottitis, thyroid neoplasm (nodules), sarcoidosis, porphyria non-acute, bipolar disorder, completed suicide, suicide attempt,cerebral ischaemia, encephalopathy, papilloedema, acute myocardial infarction, atrial fibrillation, coronary artery disease, pericarditis, pericardial effusion, venous thrombosis, pleural fibrosis, respiratory failure, pancreatic insufficiency, cholecystitis, aspermia. Other less common and rarely reported side effects are listed in the Summary of Product Characteristics. **PACKAGE QUANTITIES AND BASIC NHS COST: Packs of 336 capsules (4 inner cartons each of 84 tablets): £2,800.00. Marketing Authorisation Holder:** Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom. **Marketing Authorisation Number:** EU/1/11/704/001 **POM** **Date of review of Prescribing information: July 2011.**

Date of preparation: July 2011

Printed in England

Useful contacts

General

Transport for London (24hr)	0207 222 1234 www.tfl.gov.uk

Air travel

Heathrow Airport	0870 000 0123 www.baa.com/main/airports/heathrow
Gatwick Airport	0870 000 2468 www.baa.com/main/airports/gatwick
Luton Airport	0158 240 5100 www.london-luton.co.uk
Stansted Airport	0870 000 0303 www.baa.com/main/airports/stansted

Rail travel

National Rail information/reservations	0845 748 4950 www.nationalrail.co.uk
Eurostar trains	0870 518 6186 www.eurostar.com
Heathrow Express	0845 600 1515 www.heathrowexpress.co.uk
Gatwick Express	0870 530 1530 www.gatwickexpress.co.uk

Bus and coach travel

National Express coaches	0870 580 8080 www.nationalexpress.com
Eurolines	0870 514 3219 www.eurolines.com

Road travel

NCP	0870 606 1050 www.ncp.co.uk
Congestion charging	0845 900 1234 www.cclondon.com

The Queen Elizabeth II Conference Centre is located within London's congestion charge zone

Taxis:	London Dial-a-Ride	0207 266 6100
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CONFERENCE INFORMATION

Badges

Badges must be worn at all times to gain access to the lecture theatre, dining and exhibition areas.

Cloakroom

A staffed cloakroom is available at the Queen Elizabeth II Conference Centre. All belongings are left at the owner's risk. The Queen Elizabeth II Conference Centre and the British HIV Association do not accept responsibility for the loss of, or damage to, delegates' personal property stored in the cloakroom areas.

Accommodation

Please note that the registration fee does **not** include accommodation. A list of hotels and rates are available online on the BHIVA website (www.bhiva.org). Please note that Reservation Highway, which provides a free hotel reservation service, has been appointed the official conference accommodation bureau. The hotel allocation is limited and consequently will be administered on a first-come, first-served basis..

Book online at: **www.bhiva.org**

Queries: **Reservation Highway** · T: 01423 525577 · F: 01423 525599 · E: admin@reservation-highway.co.uk

Exhibition

Exhibition represents an integral element of the Conference, providing participants with an excellent platform for networking as well as an opportunity to gain further insight into cutting-edge technology, the latest healthcare solutions, and services within the field of HIV and GU medicine. Entrance to the exhibition hall is free for all registered delegates.

Conference Venue: Queen Elizabeth II Conference Centre

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Venue and travel

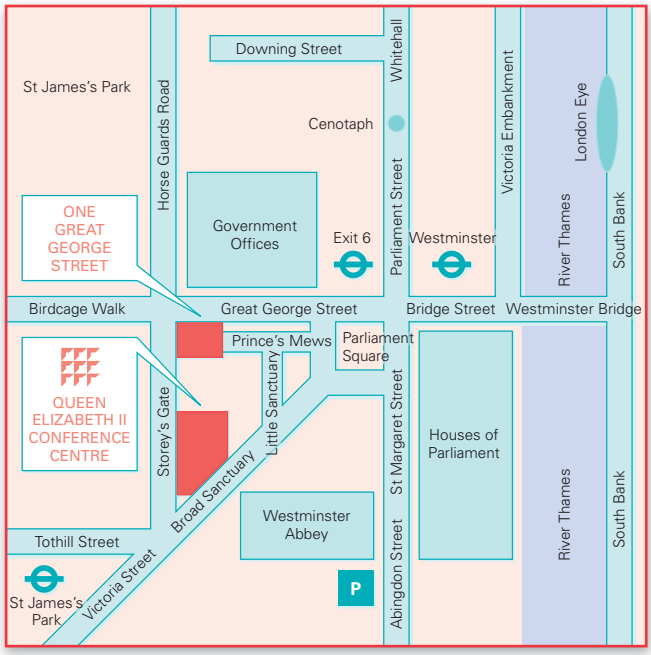
The conference venue is a short walk from **Westminster** or **St James's Park** underground stations. Please see the map for the location of these stations in relation to the **Queen Elizabeth II Conference Centre**.

Westminster and St James's Park underground stations are easily accessible from **King's Cross**, **St Pancras (Eurostar)** and **Victoria** main-line rail stations and can be accessed by the **Jubilee** line or the **Circle and District** lines. The journey from these main-line stations to Westminster or St James's Park underground stations takes approximately 10 minutes and costs approximately £4.

There are also good links to the city centre from both **Heathrow** and **Gatwick** airports. Journeys by either Heathrow or Gatwick Express take about 1 hour.

There are four car parks near to the conference venue. For further information please visit www.ncp.co.uk

Please note that the conference venue is located within the London congestion charge zone.



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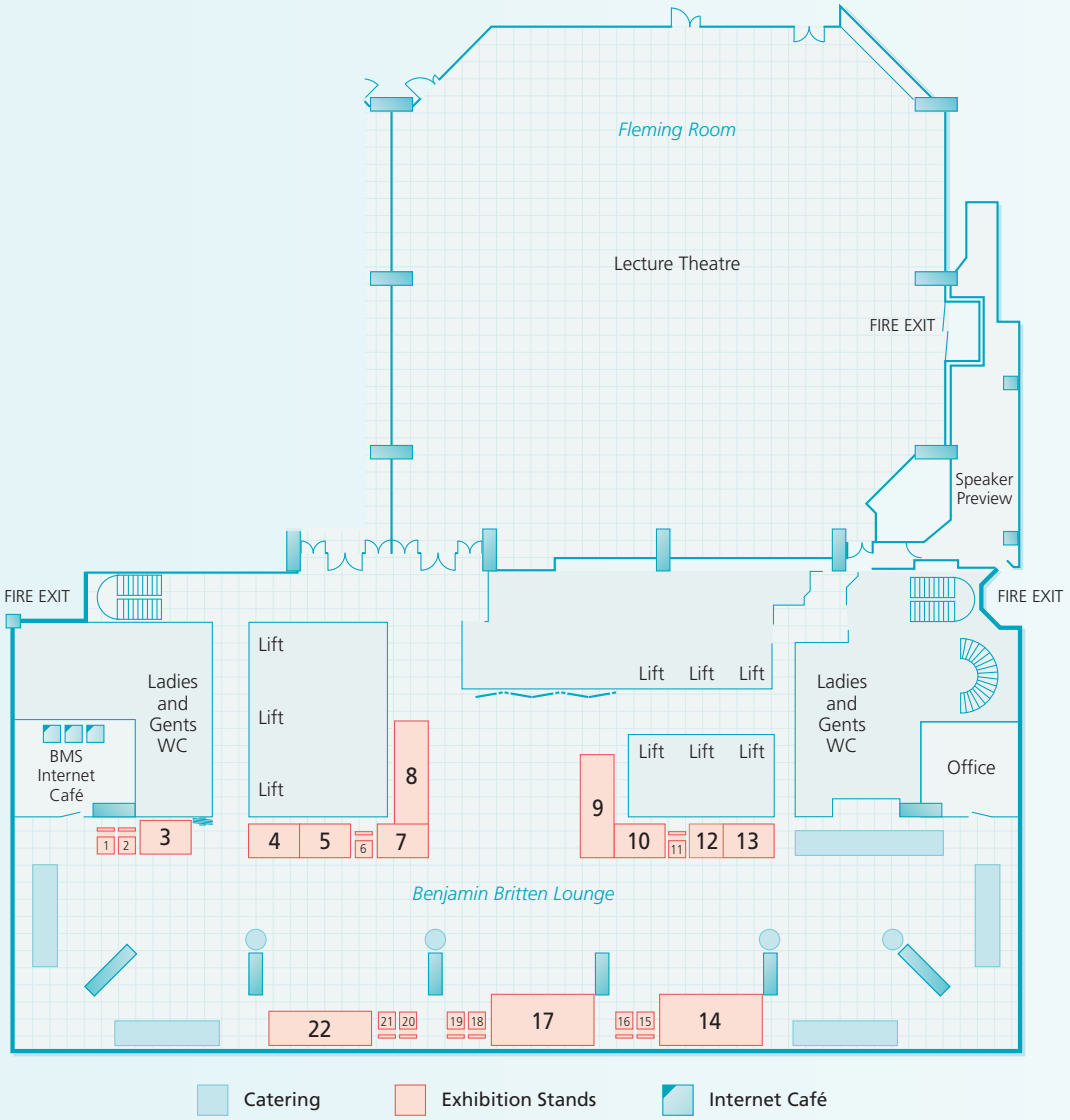
EXHIBITION LAYOUT

QUEEN ELIZABETH II CONFERENCE CENTRE, 3rd FLOOR



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PREZISTA▼
darunavir

...the most prescribed boosted PI in the UK as of October 2010[1]

- The only PI proven to offer non-inferior virological efficacy to LPV/r over 192 weeks[2-4]
- Significantly lower incidence of Grade 2-4 Diarrhoea compared to LPV[2-4]
- Comparable lipid profile to ATV[5]

Dosing regimen

Once Daily:
- ART-naïve adults and
- ART-experienced adults with no darunavir resistance associated mutations (DRV-RAMs)* and who have plasma HIV-1 RNA <100,000 copies/ml and CD4+ cell count ≥100 cells x 10^6/l

* DRV-RAMs: V11I, V32I, L33F, I47V, I50V, I54M, I54L, T74P, L76V, I84V and L89V.

Prezista 800mg once daily with ritonavir 100mg once daily taken with food

PREZISTA (2 x 400mg) with ritonavir (1 x 100mg) taken with food

Twice Daily:
All other ART-experienced adults (or if HIV-1 genotype testing is not available)

Prezista 600mg twice daily with ritonavir 100mg twice daily taken with food

PREZISTA (1 x 600mg) with ritonavir (1 x 100mg) taken with food

PREZISTA (1 x 600mg) with ritonavir (1 x 100mg) taken with food

Total pill burden will depend on overall regimen. Tablets not to actual size or scale, illustration purposes only.

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Code: UK/PRE/2011/0006
Date of Preparation: September 2011

Prescribing Information can be found overleaf.

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PHARMACEUTICAL COMPANIES OF Johnson & Johnson

PRESCRIBING INFORMATION

PREZISTA® ▼ 75 mg, 150 mg, 400 mg & 600 mg film-coated tablets
Active ingredient: 75 mg, 150 mg, 400 mg or 600 mg of darunavir (as ethanolate).
See Summary of Product Characteristics (SmPC) before prescribing.
INDICATIONS: PREZISTA, co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of patients with human immunodeficiency virus (HIV-1) infection.

PREZISTA 75 mg, 150 mg and 600 mg tablets may be used to provide suitable dose regimens:
- For the treatment of HIV 1 infection in antiretroviral treatment (ART) experienced adult patients (including highly pre treated).
- For the treatment of HIV 1 infection in ART experienced children and adolescents from the age of 6 years and at least 20 kg body weight.
  Genotypic or phenotypic testing (when available) and treatment history should guide the use of PREZISTA.

PREZISTA 400 mg tablets may be used to provide suitable dose regimens:
- For the treatment of HIV 1 infection in antiretroviral therapy (ART) naïve adults.
- For the treatment of HIV 1 infection in ART experienced adults with no darunavir resistance associated mutations (DRV RAMs) and who have plasma HIV 1 RNA < 100,000 copies/ml and CD_4+ cell count ≥ 100 cells x 106/l. In deciding to initiate treatment with PREZISTA in such ART experienced adults, genotypic testing should guide use.

DOSAGE AND ADMINISTRATION:
Therapy should be initiated by physician experienced in management of HIV. ***ART-naïve adults:*** PREZISTA 800 mg once daily with ritonavir 100 mg once daily, taken with food. ***ART-naïve children:*** Not recommended for use in this group. ***ART-experienced adults with no DRV-RAMs:*** PREZISTA 800 mg once daily with ritonavir 100 mg once daily, taken with food. ***All other ART experienced adults;*** 600 mg PREZISTA /100 mg ritonavir twice daily with food. ***ART-experienced children ≥ 20 kg and < 30 kg:*** 375 mg PREZISTA/50 mg ritonavir twice daily with food. ***ART-experienced children ≥ 30 kg and < 40 kg:*** 450 mg PREZISTA/60 mg ritonavir twice daily with food. ***ART-experienced children > 40 kg:*** 600 mg PREZISTA /100 mg ritonavir twice daily with food. Use 75 mg/150 mg PREZISTA tablets to achieve recommended 600 mg dose in this group if possibility of e.g., swallowing difficulty or specific colouring agent hypersensitivity. ***Children < 6 years of age or < 20 kg body weight:*** Not recommended. ***Elderly:*** Limited information available. Caution should be exercised. ***Hepatic impairment:*** Use with caution in patients with mild or moderate hepatic impairment and contraindicated in patients with severe hepatic impairment. ***Renal impairment:*** No dose adjustment required.

CONTRAINDICATIONS: Hypersensitivity to active substance or any excipients. Severe hepatic impairment. Combination of rifampicin/ritonavir or lopinavir/ritonavir with PREZISTA.Preparations containing St John's wort. Active substances that are highly dependent on CYP3A for clearance e.g. amiodarone, bepridil, quinidine, systemic lidocaine, alfuzosin, astemizole, terfenadine, dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, pimozide, sertindole, triazolam, orally administered midazolam, sildenafil (in treatment of pulmonary arterial hypertension), simvastatin and lovastatin.

SPECIAL WARNINGS AND PRECAUTIONS: Regular assessment of virological response is advised. Perform resistance testing if lack of/loss of virological response. Do not use PREZISTA/rtv 800/100 mg once daily dose regimen in ART-experienced patients with one or more DRV-RAMs. Advise patients that current antiretroviral therapy does not cure HIV and precautions should be taken to avoid transmission. Do not use in children < 6 years of age or weighing < 20 kg. Severe skin reactions: Discontinue PREZISTA/rtv immediately if signs or symptoms of severe skin reactions develop. Stevens-Johnson Syndrome and toxic epidermal necrolysis reported rarely. Rash: In clinical studies, mild to moderate rash more common in treatment-experienced patients receiving both PREZISTA + raltegravir compared to patients on either PREZISTA or raltegravir alone. Patients with known sulphonamide allergy: Contains a sulphonamide moiety; caution advised. Hepatotoxicity: Drug-induced hepatitis has been reported. Patients with pre-existing liver dysfunction including chronic active hepatitis B or C have increased risk of liver function abnormalities including severe/potentially fatal hepatic adverse events and should be monitored. Prompt interruption/discontinuation of treatment if liver disease worsens. Haemophiliac patients: Possibility of increased bleeding. Immune reactivation syndrome: An inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise in immune reactive patients with severe immune deficiency at start of combination antiretroviral therapy (CART). Other: Onset/exacerbation of diabetes mellitus or hyperglycaemia reported. Lipodystrophy and metabolic abnormalities. Consider measurement of fasting serum lipids and blood glucose and manage as appropriate. Patients with advanced HIV disease and/or long-term exposure to CART may develop osteonecrosis. Life-threatening/fatal drug interactions reported in patients treated with colchicine and powerful CYP3A and Pgp inhibitors. Patients with renal or hepatic impairment should not be given colchicine with DRV/r. PREZISTA 400 mg & 600 mg tablets contain sunset yellow FCF (E110) which may cause allergic reaction.

INTERACTIONS: Refer to the SmPC for full details before initiating therapy. Interaction studies have only been performed in adults. **Medicinal products that affect darunavir/ritonavir exposure:** Darunavir/ritonavir must not be co-administered with medicinal products that are highly dependent on $CYP3A_4$ for clearance and for which increased systemic exposure is associated with serious and/or life-threatening events. Refer to "Contraindications" for more details. **Medicinal products that are affected by the concomitant use of darunavir/ritonavir:** PIs –Lopinavir/ritonavir contraindicated. Saquinavir: not recommended. Indinavir: dose adjustment may be required. Atazanavir: can be used with darunavir/ritonavir. The efficacy and safety of the use of darunavir/ritonavir and any other PI not established (e.g. fos (amprenavir), nelfinavir and tipranavir). Generally, dual therapy with PIs not recommended. **NNRTIs :** Efavirenz: if in combination with PREZISTA/rtv, the PREZISTA/rtv 600/100 mg twice daily regimen should be used. Clinical monitoring for CNS toxicity may be required. Etravirine, nevirapine: no dose adjustment required. **NRTIs:** Tenofovir: monitoring of renal function may be required. No interactions expected with zidovudine, zalcitabine, emtricitabine, stavudine, lamivudine, didanosine and abacavir. **Non-antiretroviral products – Do not use:** phenobarbital, phenytoin, voriconazole, salmeterol, sildenafil/ tadalafil (treatment of pulmonary arterial hypertension). Monitoring required/possible dose adjustments: carbamazepine, clarithromycin, ketoconazole, itraconazole and clotrimazole, warfarin (monitor INR), calcium channel blockers, oestrogen hormone replacement therapy, cyclosporine, tacrolimus and sirolimus, methadone coadministration, parenteral midazolam, atorvastatin, rosuvastatin, pravastatin PDE-5 inhibitors, rifabutin, colchicine, bosentan. Maraviroc: dose should be 150 mg twice daily. Careful titration required: digoxin, SSRI's. No dose adjustment: H2-receptor antagonists, proton pump inhibitors. Alternative or additional contraceptive measures required: oestrogen-based contraceptives. Caution: dexamethasone. Not recommended: fluticasone,

PREGNANCY AND LACTATION: Use during pregnancy only if potential benefit justifies potential risk. HIV infected women must not breast-feed their infants under any circumstances.

SIDE EFFECTS: ***Refer to SmPC for full details of side effects.*** Safety profile in children and adolescents is similar to that in adult population. ***Very common:*** diarrhoea. ***Common:*** lipodystrophy, hypertriglyceridaemia, hypercholesterolaemia, hyperlipidaemia, insomnia, headache, peripheral neuropathy, dizziness, vomiting, nausea, abdominal pain, increased blood amylase, dyspepsia, abdominal distension, flatulence, increased alanine aminotransferase, increased aspartate aminotransferase, rash, pruritus, asthenia, fatigue. ***Uncommon:*** tthrombocytopenia, neutropenia, anaemia, immune reconstitution syndrome, drug hypersensitivity, diabetes mellitus, gout, anorexia, decreased appetite, weight changes, hyperglycaemia, insulin resistance, depression, confusional state, disorientation, anxiety, altered mood, sleep disorder, abnormal dreams, lethargy, paraesthesia, hypoaesthesia, somnolence, conjunctival hyperaemia, vertigo, myocardial infarction, angina pectoris, prolonged electrocardiogram QT, hypertension, dyspnoea, cough, pancreatitis, gastritis, gastrooesophageal reflux disease, aphthous stomatitis, retching, dry mouth, abdominal distension, flatulence, constipation, hepatitis, cytolytic hepatitis, hepatic steatosis, increased enzyme levels, allergic dermatitis, urticaria, hyperhidrosis, night sweats, alopecia, osteoporosis, myalgia, arthralgia, pain in extremity, renal failure, nephrolithiasis, increased blood creatinine, decreased creatinine renal clearance, proteinuria, bilirubinuria, erectile dysfunction, gynaecomastia, pyrexia, chest pain, peripheral oedema, malaise. ***Patients co infected with hepatitis B and/or hepatitis C virus:*** more likely to have baseline and treatment emergent hepatic transaminase elevations than those without chronic viral hepatitis.
LEGAL CATEGORY: POM.

PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBER & BASIC NHS COSTS:
75 mg tablets: 1 bottle containing 480 tablets. EU/1/06/380/005. £ 446.70.
150 mg tablets: 1 bottle containing 240 tablets. EU/1/06/380/004. £ 446.70.
400 mg tablets: 1 bottle containing 60 tablets. EU/1/06/380/003. £297.80
600 mg tablets: 1 bottle containing 60 tablets. EU/1/06/380/002. £446.70.

MARKETING AUTHORISATION HOLDER: JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

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Prescribing information last revised: June 2011

PIVER: JUN 2011

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Janssen-Cilag Ltd on 01494 567447.

References:
1. IMS PI Market and Cash share data. August 2011
2. Mills AM et al. AIDS 2009; 23(13): 1679-88.
3. Orkin C et al. Presented at the 10th International Congress on Drug Therapy in HIV Infection, 2010; Glasgow. Poster no. 3. Available upon request.
4. Llibre JM. AIDS Rev 2009; 11: 215-22.
5. Overton T et al. Metabolik Poster; presented at the 10th International Congress on Drug Therapy and HIV Infection (HIV 10), Glasgow, UK, 2010.Poster no. 74. Available upon request.

Date of preparation: September 2011

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FORTHCOMING EVENTS

HIV/AIDS at 30: *Back to the Future*
BHIVA/Wellcome Trust Multidisciplinary Event *to mark* World AIDS Day
Thursday 1 December 2011
Wellcome Collection Conference Centre, London

BHIVA Inpatient General Medicine for HIV Physicians Course
Tuesday 6 December 2011
Royal Society of Medicine, London

HIV in Pregnancy
Royal College of Obstetricians and Gynaecologists/British HIV Association Multidisciplinary Conference
Friday 20 January 2012
Royal College of Obstetricians and Gynaecologists
London

Growing up with HIV
Paediatrics and Child Health Section RSM *meeting in association with* Children's HIV Association (CHIVA)
Tuesday 21 February 2012
Royal Society of Medicine, London

BHIVA 'Best of CROI' Feedback Meetings
From w/c 19 March 2012
London | Gateshead | Haydock | Edinburgh | Birmingham

18th Annual Conference of the British HIV Association (BHIVA)
18–20 April 2012
The International Convention Centre
Birmingham

6th Annual Conference of the Children's HIV Association (CHIVA)
Friday 18 May 2012
Birmingham

14th Annual Conference of the National HIV Nurses Association (NHIVNA)
14–15 June 2012
Manchester Conference Centre

For further information on these events, please contact:
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1 Mountview Court, 310 Friern Barnet Lane, London N20 0LD
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BIOGRAPHIES

Kosh Agarwal is a Consultant Hepatologist and Transplant Physician at the Institute of Liver Studies, King's College, London. He is also Lead for the Viral Hepatitis Service, which is the largest treatment centre for viral hepatitis in the UK. Dr Kosh Agarwal graduated from Newcastle University. His postgraduate training was undertaken in Newcastle with the majority of his clinical and research training at the Regional Liver and Transplant Unit. Prior to his appointment at King's, he was a Consultant & Honorary Senior Lecturer at the Regional Liver & Transplant Unit in Newcastle. Dr Agarwal also spent a year at the Division of Liver Diseases, Mount Sinai, New York furthering his viral hepatitis expertise. He is an investigator for several ongoing studies evaluating the safety and efficacy of various antiviral treatment regimens for chronic hepatitis B & C.

Jane Anderson (Homerton University Hospital NHS Foundation Trust and Barts and the London School of Medicine and Dentistry): Working in East London, Professor Anderson's clinical practice and research interest focus on HIV in ethnic minority and migrant populations in the UK, with a special interest in the care of women with HIV. She has been elected Chair of the British HIV Association (2011–2014) and is currently a member of the BHIVA Guidelines and Conference subcommittees.

Rachel Baggaley is a member of the HIV Department at WHO working on a wide range of issues, including HIV testing and counselling (HTC) related to adolescents. She began working on HIV in the late 1980s, working with IDU. From 1992 she worked in Zambia setting up HTC services and care and support services for people with HIV. She then worked with WHO/UNAIDS on the first ART guidelines, HIV testing issues and prevention of mother-to-child transmission. From 2002–2010 she led the HIV work of a UK-based international NGO supporting around 300 community-based organisations working on HIV in developing countries, with a particular focus on post-conflict countries and fragile states.

Tony Barnett is Professorial Research Fellow at the LSE and Honorary Professor at LSHTM. An interdisciplinary social scientist with training in economics, sociology, social anthropology and political science, he specialises in the social sciences of infectious diseases. He has studied the social and economic impact and implications of HIV/AIDS in Africa and elsewhere since 1986.

Sanjay Bhagani is a Consultant Physician in Infectious Diseases/HIV Medicine and General (Internal) Medicine at the Royal Free Hospital, London. He has a sub-specialty interest in managing patients with HIV and hepatitis co-infection and has served on the HIV/hepatitis co infection management guidelines committees of EACS and BHIVA. He is committed to education and training in HIV medicine for doctors in the developing world and has been involved in delivering training programmes in East Africa and the Indian subcontinent. He is passionate about fostering further educational links with the developing world.

Gus Cairns works for NAM, as one of its three staff writers, where he is Editor of *HIV Treatment Update* and of the *Preventing HIV* pages at www.aidsmap.com. He is a former patient representative on the Executive Committee of BHIVA and is currently in the Guidelines Writing Group. He is also a patient representative to the CHAARM microbicides research consortium, a member of the Steering Committee of the Global Forum for MSM and HIV, and a member of the European AIDS Treatment Group. Originally a social worker with homeless youth, he first became involved in the HIV sector after recovery from HIV-related illness in 1997, and was editor of *Positive Nation*, the UK's first magazine for people with HIV. Gus is also an accredited psychotherapist and runs a small private practice.

Mas Chaponda is a Clinical Lecturer at the University of Liverpool, Institute of Translational Medicine and Honorary Specialist Registrar in Infectious Diseases and Clinical Pharmacology. His interests include pharmacogenetics, adverse drug reactions and drug interactions. For the last three years he has been looking at genetic and environmental predisposing factors for nevirapine drug hypersensitivity.

Ed Clarke is a Clinical Lecturer in Paediatrics working in infectious diseases at Bristol Children's Hospital and the University of Bristol.

Pierre Corbeau is Professor of Medicine in Immunology. He is currently Head of the Immunology Branch at the University Hospital of Nîmes and Group Leader at the Institute for Human Genetics of the CNRS in France. He is active in research assessing the roles of coreceptors and the importance of immune activation in HIV infection.

Geoffrey Dusheiko is a hepatologist. He is the Lead Clinician on the Viral Hepatitis Service at the Royal Free Hospital, London. His major interests are in the epidemiology, natural history, pathogenesis and treatment of chronic viral hepatitis. He has an international reputation as a clinical and academic hepatologist, and has published widely in the field of viral hepatitis and antiviral therapies. Professor Dusheiko is an academic physician with a large clinical input.

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BIOGRAPHIES

Claire Foreman is a Senior Commissioning Manager at the London Specialised Commissioning Group and Lead Commissioner for HIV in London. Her role includes supporting the Perinatal, Paediatric & Young People's Sub Group of London's HIV Consortium, membership of the CHIPS Steering Committee, and leading a review of paediatric and adult HIV services in London.

Caroline Foster is a Consultant in Adolescent Infectious Diseases/HIV Transitional Care at Imperial College Healthcare NHS Trust. She is the current Chair of HYPNET (HIV in Young People Network, www.hypnet.org.uk) and her research interests include the long-term neurocognitive, cardiovascular and reproductive impact of perinatally acquired HIV infection and of antiretroviral therapy.

Brian Gazzard is Professor of HIV Medicine and Clinical Research Director at the Chelsea and Westminster Hospital, London. His main interests are in gastrointestinal manifestations of HIV disease and in antiretroviral therapy. In 2002, in recognition of the achievements of the HIV/GUM unit at the Chelsea and Westminster Hospital, Professor Gazzard was awarded a prize for clinical leadership at the 20th anniversary celebration of the Terrence Higgins Trust, and the Outstanding Achiever for Health Award. Professor Gazzard was the Founding Chair of BHIVA.

Yvonne Gilleece is a Consultant in HIV & Genitourinary Medicine at Brighton & Sussex University Hospitals NHS Trust and an Honorary Senior Lecturer at Sussex University. She is the Lead for HIV in Pregnancy and Hepatitis B as well as a clinical supervisor for a PhD on HIV and Bone. She is a member of the BASHH HIV Special Interest Group and has been an author on the BHIVA guidelines for hepatitis and for HIV-2.

Robert (Bob) Grant is a Senior Investigator at the Gladstone Institute of Virology and Immunology and an Associate Professor of Medicine at the University of California San Francisco. He has over 26 years of experience with AIDS clinical care and research. Dr Grant is the Protocol Chair for the iPrEx study.

Djamel Hamadache qualified as a general nurse in 1998 and as a paediatric nurse in 2006. Through his career, he has developed a strong interest in HIV and has since been involved in paediatric and adult clinical care, coordination of research trials and a few projects in the voluntary sector. He is currently working as a Paediatric Nurse Specialist. In addition, Djamel has recently taken a new role as the CHIVA website Health Manager, ending almost 4 years of commitment as the Nurse Representative on the CHIVA Executive Committee.

Emily Hamblin coordinates the Children and Young People HIV Network based at the National Children's Bureau. The HIV Network is for professionals from all sectors who are concerned with meeting the needs of children and young people living with or affected by HIV. It develops and disseminates policy and practice, provides a voice for young people through participation work, runs training and events, facilitates networking and disseminates information. Emily is also a member of the CHIVA Executive Committee.

Margaret Johnson is the Clinical Director of the Royal Free Centre for HIV Medicine and is Professor of HIV Medicine at University College London. She has been involved in the management of women with HIV infection since 1989 when she was appointed the first HIV physician in the UK. One of her first projects on appointment was the development of a designated HIV clinic for women. More recently she chaired the British HIV Association from 2004 to 2008. Together with Professor Jane Anderson she has chaired BHIVA guidelines for the management of women with HIV.

Julie Lanigan is a paediatric dietitian specialising in research at the Medical Research Council – Childhood Nutrition Research Centre, UCL Institute of Child Health, London. Since 1998 she has been a key investigator in a range of clinical trials which focus on investigating the role of nutrition in the early origins of obesity and cardiovascular disease. Current projects include a multicentre clinical trial investigating effects of nutrition in early life on later obesity and CVD risk, and a randomised controlled trial of an intervention to prevent obesity in preschool children. Julie holds an honorary contract at Great Ormond Street Hospital and provides dietetic support for the HIV Family Clinic when possible. She is a co-founder of mini-DHIVA, a sub-group of the BDA specialist group for Dietitians working in HIV/AIDS (DHIVA) and she is Dietetic Co ordinator for the CHIVA-Africa charity.

Sebastian Lucas has studied the morbid anatomy of HIV/AIDS, in Africa and the UK, since the mid-1980s. His particular interest is in correlating clinical and imaging diagnoses in patients with the pathology and the treatment. Professor Lucas is ex-Chair of the BHIVA Education and Scientific Subcommittee, and sits on the Conferences Subcommittee. He works in the Department of Histopathology at St Thomas' Hospital, London.

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BIOGRAPHIES

Andrew McMichael qualified in Medicine from Cambridge and St Mary's Hospital Medical School in 1968 and obtained a PhD in Immunology at NIMR in 1974. He first showed that virus specific CD8 T cells were HLA restricted and, later, Alain Townsend in his group demonstrated that virus derived peptides were presented to T cells by MHC class I molecules. Since 1987 he has studied the T cell response to HIV, with a particular interest in virus escape from T cell recognition during acute infection. For the last 15 years he has focused on HIV vaccines. His group have designed and tested two candidate HIV vaccines in Phase I clinical trials. His group has also been involved in developing novel methods for measuring T cell responses, such as HLA tetramer staining. He is Director of the Weatherall Institute of Molecular Medicine in Oxford University and founded the Medical Research Council Human Immunology Unit. He was knighted in 2008 for services to medical sciences and is a Fellow of the Royal Society.

Barbara McGovern is an Associate Professor at Tufts University School of Medicine and is the Director of the Viral Hepatitis Clinic at Shattuck Hospital in Massachusetts. She is a member of the Antiviral Advisory Committee for the Food and Drug Administration and is an Associate Editor for *Clinical Infectious Diseases* and Deputy Editor of *UpToDate*.

Diane Melvin is a Consultant Clinical Psychologist who has worked for the past 20 years as part of a multidisciplinary service for children with HIV infection and their families attending the Family Clinic at St Mary's Hospital in London. During this time she has taken an active role in promoting the psychological needs of children living with HIV both nationally and in Africa. Diane's interests are in developmental and learning outcomes for these children, their understanding about HIV and how to enhance their coping. She is a founder member of the PHP (Paediatric HIV Psychology group in the UK) and was a member of the CHIVA Executive Committee until April 2011.

Graeme Moyle is currently the Director of HIV Research Strategy at the Chelsea and Westminster Hospital in London. Dr Moyle received his medical degree (MB, BS) and doctorate (MD) from the University of Adelaide. He co-ordinates phase 2–4 research at the Chelsea and Westminster Hospital together with the clinical management of a large cohort of persons with HIV infection. His research interests include the clinical development of new antiretrovirals, evidence-based use of antiretroviral agents, metabolic and morphologic complications of HIV disease. He is a member of the IAS core faculty, has served on the British HIV Association Treatment Guidelines Writing Committee, and is a medical adviser for the UK National AIDS Manual. In addition, Dr Moyle is Editor of *The Journal of Viral Entry*, the past editor (2000–2006) of the HIV section of *Current Opinion in Infectious Diseases* and on the Editorial Board of *AIDS Reviews*, *HIVandhepatitis.com* and Medscape. He is an expert adviser for *TheBody.com* and Medscape as well as a regular columnist on *The AIDS Reader*.

Mark Nelson is a Consultant Physician at the Chelsea and Westminster Hospital, London. Dr Nelson sits on the Executive Committee of the British HIV Association. He is Chair of the BHIVA Hepatitis Special Interest Group. He is a trustee of St Stephen's AIDS Trust, and is Head of Overseas Development and Education for this charity. He has been awarded a visiting professorship at the Aga Khan Hospital, Nairobi, Kenya and most recently the Certificate of Merit by the government of Vietnam.

Emma Page is an SpR HIV/GUM at Chelsea and Westminster Hospital, London, with a specialist interest in HIV/HCV co-infection. She has just completed two years' research for MD (Res) with Imperial College London on HIV/HCV co-infection with the Immunology Department.

Nina Pearson is a part-time general practitioner in a large practice in Luton and Clinical Lead for Gynaecology and Sexual Health for NHS Luton. Lea Vale Medical Group is one of two in the town offering an enhanced primary care service for HIV-positive patients.

Deenan Pillay is Professor of Virology at UCL, Head of the Research Department of Infection and Honorary Consultant Virologist at University College London Hospital. He is Director of the NIHR UCLH/UCL Comprehensive Biomedical Research Centre, and Research Director and Infectious Diseases Programme Director for UCL Partners. He is also a Senior Investigator for the National Institute for Health Research. His research focuses on the biological and clinical implications of HIV drug resistance, and the molecular epidemiology of HIV. In addition, he works on international studies of HIV treatment rollout, and is Director of one of the five WHO Specialist Reference Laboratories for HIV drug resistance.

Frank Post is an Infectious Diseases Physician at King's College Hospital and Clinical Senior Lecturer in HIV Medicine at King's College London. His clinical and research interests include the effects of HIV and antiretroviral therapy on kidney and bone, solid organ transplantation in HIV infection, and mycobacterial infections including multi-drug resistant tuberculosis.

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BIOGRAPHIES

Anton Pozniak worked as a Consultant Physician in Zimbabwe, where he researched for his doctorate in TB/HIV, moving back to the UK in 1991. He ran the HIV Research Unit at King's College, London before moving to his current position as Consultant Physician/Senior Lecturer at the Chelsea and Westminster Hospital in 1998. He has been made a Life Member of the British HIV Association, has helped write the British HIV Association (BHIVA) anti-viral HIV guidelines and chairs the TB/HIV Guidelines Committee. He is on the Expert Advisory Group on AIDS for the UK Department of Health. He is an Executive Committee member of the European AIDS Clinical Society and is on the Governing Council of the IAS. He is Vice Chair of the European AIDS trial network NEAT. He has published widely on clinical aspects of HIV treatment and care.

Jude Ragan trained and qualified as a teacher of children with special needs in 1972, and has since worked in the field of autism, either as a teacher, a manager or as an inspector with Ofsted. She has been headteacher of four special schools, all of which catered for students with autism. Her present school, Queensmill in Hammersmith and Fulham, caters for children and young people with autism from the ages of 2–19. It has been judged to be outstanding in the last two Ofsted inspections. Additionally, it is setting up autism units in local mainstream schools.

Andri Rauch is a Specialist in Infectious Diseases and Internal Medicine at the University Hospital Berne, Switzerland. After completion of his medical training, he joined the Murdoch University in Western Australia for a post-doctoral fellowship to study the influence of host genes on HCV evolution. His current research focuses on host–viral interactions in HIV and hepatitis C co-infection.

Elizabeth Shaw is the Chair of the multiagency Standards for Psychological Support in HIV representing the British Psychological Society. She is a Consultant Clinical Psychologist working in the field of sexual health and HIV for the last 16 years. She currently works in Haringey, North London, in St Ann's Sexual Health Centre and the North Middlesex Hospital HIV Unit. She was the Chair of the Faculty of Sexual Health and HIV of the Division of Clinical Psychology and has an interest in furthering psychological perspectives on helping people with HIV live with HIV.

Eunice Sinyemu is the Head of Policy and Deputy CEO at African HIV Policy Network. She has previously worked for HIV Scotland as Information and Development Officer for the African and Minority Ethnic HIV Project. Prior to working for HIV Scotland, Eunice worked for Waverley Care as an African Outreach worker and conducted a needs assessment research on Africans living with HIV in Scotland. She trained as a teacher in Zambia and has completed an MSc in Africa and International Development at the University of Edinburgh. She also has an MSc in Social Development and Health from Queen Margaret University in Edinburgh as well as an Honours Degree in Business Studies. Eunice was one of the group members of Quality Improvement Scotland, looking at HIV prevention strategy for the most at-risk groups in Scotland. She is a trustee of UK Consortium on AIDS and International Development, Waverley Care. As a member of UK Community Advisory Board, she is on the BHIVA World AIDS Day planning group. She has previously been a trustee of the Church of Scotland's HIV project and Lothian Africa Health Links.

Erasmus Smit is a Consultant Medical Virologist at the HPA Microbiological Services Birmingham and Heart of England NHS Foundation Trust. His clinical and research interests are HIV therapy, resistance and its interpretation.

Steve Taylor is a Consultant Physician in Sexual Health and HIV Medicine at Birmingham Heartlands Hospital, and an Honorary Senior Clinical Lecturer at the University of Birmingham. He has been the Lead Consultant for the Birmingham Heartlands HIV Service since 2004. He obtained his PhD in 2002 with a thesis on 'The Sexual Transmission of HIV'. During this time he developed an interest in HIV transmission, resistance and HIV clinical pharmacology, areas in which he has presented and published widely.

Steve Welch has been a Consultant in Paediatric HIV and Infectious Diseases at Heartlands Hospital, Birmingham since 2006. He has helped establish adolescent transition services regionally, is one of the authors of the 2009 PENTA HIV treatment guideline, and is a member of CHIVA's guidelines group. Dr Welch is a member of the PENTA Steering Committee, and is jointly in charge of PENTA's training activities. He has been elected Chair of the Children's HIV Association (2011–2014).

Ian Williams is a Senior Lecturer at University College London and an Honorary Consultant Physician at CNWL NHS Trust and University College London Hospitals. He has extensive clinical and research experience in HIV medicine. He was a member of the BHIVA Executive Committee between 1996 and 2003, and between 2006 and 2011. He served as Honorary Treasurer of the Association from 2000 to 2003, became Chair-Elect in September 2007 and served as Chair of the Association between 2008 and 2011.

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Refer to Summary of Product Characteristics for full information
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Once daily dosing should be limited to those adult patients having only very few protease inhibitor (PI) associated mutations (i.e. less than 3 PI mutations in line with clinical trial results, see section 5.1 for the full description of the population) and should take into account the risk of a lesser sustainability of virologic suppression and higher risk of diarrhoea compared to twice daily dosing. **Children older than 2 years:** *Kaletra Oral Solution:* 230/57.5 mg/m^2 twice daily with food. Maximum dose of 400/100 mg twice daily. If co-administered with efavirenz or nevirapine, a dose increase to 300/75 mg/m^2 twice daily should be considered. Body Surface Area (BSA) is calculated as: BSA (m^2) = √(Height (cm) x Weight (kg) / 3600). *Kaletra 200mg/50mg film-coated tablets:* Children weighing 40kg or greater with a BSA ≥ 1.4 m^2 and who are able to swallow tablets, may take 2 tablets twice daily with or without food. Children with a BSA <1.4 m^2, Kaletra oral solution or 100/25mg tablets is recommended. *Kaletra 100mg/25mg film-coated tablet:* Children with BSA ≥0.5 to <0.9 m^2, 2 tablets twice daily. Children with BSA ≥0.9 to < 1.4 m^2, 3 tablets twice daily. The adult dose of Kaletra tablets (400/100 mg twice daily) may be used in children 40 kg or greater or with a greater than 1.4 m^2. Concomitant therapy with efavirenz or nevirapine: BSA ≥0.5 to <0.8 m^2, 2 tablets (200/50mg) twice daily. BSA ≥0.8 to <1.2, 3 tablets (300/75mg) twice daily. BSA ≥1.2 to <1.4, 4 tablets (400/100mg) twice daily. BSA≥ 1.4 m^2, 5 tablets (500/175mg) twice daily. If more convenient for patients, Kaletra 200/50mg tablets and Kaletra 100/25mg tablets may be combined to achieve the recommended dose. Kaletra dosed once daily has not been evaluated in paediatric patients. **Contraindications:** Hypersensitivity to lopinavir, ritonavir or any of the excipients. Severe hepatic insufficiency. Do not administer with medicinal products highly dependent on CYP3A for clearance, including: astemizole, terfenadine, oral midazolam, triazolam, cisapride, pimozide, amiodarone, ergot alkaloids, lovastatin, simvastatin, vardenafil and sildenafil used for the treatment of pulmonary hypertension. Do not administer with St. John's Wort (*Hypericum perforatum).* Kaletra oral solution contraindicated in children under 2 years, pregnant women, patients with hepatic or renal failure, patients treated with disulfiram or metronidazole due to risk of toxicity from excipient propylene glycol. **Precautions and Warnings:** Patients with hepatic impairment, renal impairment, hepatitis B or hepatitis C. Haemophiliac patients should be made aware of the possibility of increased bleeding. Pancreatitis. Combination antiretroviral therapy (CART) has been associated with lipodystrophy. Immune reactivation syndrome may occur, especially in patients with severe immune deficiency at initiation of CART. Protease inhibitors are also associated with metabolic abnormalities (i.e. hypertriglyceridaemia, hypercholesterolaemia, insulin resistance and hyperglycaemia, new onset diabetes mellitus, or exacerbation of existing diabetes mellitus). Cases of osteonecrosis have been reported in patients with advanced HIV-disease and/or long-term exposure to CART. Rare reports of 2nd or 3rd degree atroventricular block in patients with underlying structural heart disease and pre-existing conduction system abnormalities or in patients receiving drugs known to prolong the PR interval (such as verapamil or atazanavir) have been reported in patients receiving Kaletra. Supratherapeutic doses of Kaletra (800/200mg twice daily) have been shown to increase the QTcF interval. Patients taking oral solution who have renal impairment or decreased ability to metabolise propylene glycol should be monitored for adverse reactions relating to propylene glycol toxicity. The oral solution contains alcohol (42% v/v). Please refer to Interaction section for precautions with other medicinal products. **Interactions:** Lopinavir and ritonavir are inhibitors of the P450 isoform CYP3A and are likely to increase plasma concentrations of products primarily metabolised by CYP3A. The combination of Kaletra with atorvastatin is not recommended. If strictly necessary the lowest possible dose of atorvastatin should be used with safety monitoring. If Kaletra is used concurrently with rosuvastatin, exercise caution and consider reduced doses. If treatment with an HMG-CoA reductase inhibitor is indicated, fluvastatin or pravastatin is recommended. Co-administration with sildenafil or tadalafil for the treatment of erectile dysfunction can substantially increase these drugs' concentrations. Concomitant administration with glucocorticoids/corticosteroids metabolised via CYP3A (e.g. fluticasone propionate or budesonide) is not recommended unless benefit outweighs the risk of systemic corticosteroid effects. Medicinal products known to induce QT interval prolongation (e.g. chlorpheniramine, quinidine, erythromycin, clarithromycin) should be used with caution. Dose reduction of clarithromycin should be considered in patients with renal impairment. Caution in administering clarithromycin with Kaletra to patients with impaired hepatic or renal function. Alternative/additional contraceptive measures needed when co-administered with oestrogen-based oral contraceptives. Kaletra may reduce zidovudine and abacavir plasma concentrations and can increase tenofovir concentrations with potentially increased tenofovir associated adverse events, including renal disorders. Increased dosages of Kaletra tablets to 500/125 mg twice daily should be considered when co-administered with nevirapine or efavirenz. Dual therapy with protease inhibitors is generally not recommended, for further information refer to SmPC. Appropriate doses of indinavir and nelfinavir have not been established when co-administered with Kaletra. No dose adjustment is necessary when Kaletra is administered with saquinavir. Careful monitoring of adverse effects (notably respiratory depression but also sedation) is recommended when fentanyl is concomitantly administered with Kaletra. Concomitant administration of fosamprenavir and Kaletra is not recommended. Concentrations of antiarrhythmic drugs, dihydropyridine calcium channel blockers and anticancer agents (eg vincristine, vinblastine, dasatinib, nilotinib) may be increased resulting in the potential for increased adverse events associated with these agents. Caution and monitoring when co-administering Kaletra with digoxin as digoxin levels might increase. Low dose ritonavir (200mg twice daily) increased trazodone concentrations that led to increases in trazodone-related adverse events. It is not known whether co-administration of Kaletra and trazodone has the same effect and this combination should be used with caution. Due to decreases in bupropion concentrations, bupropion efficacy might be reduced therefore coadministration should be closely monitored. Warfarin concentrations may be affected. Anticonvulsants may decrease lopinavir concentrations. Caution and monitoring when administering carbamazepine, phenobarbitol and phenytoin with Kaletra. High doses of ketoconazole or itraconazole (>200 mg/day) are not recommended. Do not co-administer voriconazole and Kaletra unless benefit outweighs the risk of reduced voriconazole levels. Dexamethasone may decrease lopinavir concentrations. Cyclosporin, sirolimus, tacrolimus and clarithromycin concentrations may be increased. Kaletra may lower plasma concentrations of methadone. Rifabutin dose reduction of 75 % is recommended when administered with Kaletra. Rifampicin causes large decreases in lopinavir concentrations and co-administration is not recommended. Kaletra increases the AUC of midazolam 13 fold (oral midazolam) to 4 fold (parenteral midazolam) and should not be co-administered with oral midazolam and extreme caution should be used when co-administered with parenteral midazolam. Kaletra must not be administered once daily in combination with efavirenz, nevirapine, amprenavir, nelfinavir, carbamazepine, phenobarbital or phenytoin. **Side-effects:** *Adults: Very common side effects (> 1/10):* diarrhoea, nausea and upper respiratory tract infection. *Common side effects (> 1/100, < 1/10):* lower respiratory tract infection, skin infections including folliculitis and furuncle, anaemia, leucopenia, neutropenia, lymphadenopathy, hypersensitivity including urticaria and angioedema, blood glucose disorders including diabetes meelitus, hypertriglceridemia, hypocholesteremia, weight decreased, decreased appetite, anxiety, headache (including migraine), neuropathy (including peripheral neuropathy, dizziness, insomnia, hypertension, pancreatitis, gastrooesophageal reflux disease, gastroenteritis and colitis, abdominal pain (upper and lower), abdominal distension, dyspepsia, haemorrhoids, flatulence, hepatitis including AST, ALT and GGT increases, lipodystrophy including facial wasting, rash including maculopapular rash, dermatitis/rash including eczema and seborrheic dermatitis, night sweats, pruritis, myalgia, musculoskeletal pain including arthralgia and back pain, muscle disorders such as weakness and spasms, erectile dysfunction, menstrual disorders – amenorrhoea, menorrhagia and fatigue including asthenia. Potentially serious *uncommon side effects (> 1/1000, < 1/100):* immune reconstitution syndrome, cerebrovascular accident, convulsion, atherosclerosis such as myocardial infarction, atrioventricular block, tricuspid valve incompetence, deep vein thrombosis, gastrointestinal haemorrhage, hepatomegaly, cholangitis, vasculitis, rhabdomyolysis, osteonecrosis, creatinine clearance decreased and nephritis. Post-marketing surveillance experience: - Stevens-Johnson syndrome, erythema multiforme and jaundice.In paediatric patients the nature of the safety profile is similar to that seen in adults.Prescribers should consult the summary of product characteristics for further information on side effects. **Pregnancy and lactation:** There are no adequate and well-controlled studies of Kaletra in pregnant women. The prevalence of birth defects after any trimester exposure to lopinavir is comparable to the prevalence observed in the general population. No pattern of birth defects suggestive of a common aetiology was seen. It is not known whether Kaletra (oral solution/tablet) is excreted in human milk. HIV infected women must not breast-feed their infants under any circumstances to avoid transmission of HIV. **Overdosage:** Treat by general supportive measures and if indicated, emesis, gastric lavage or administration of activated charcoal. **Legal category:** POM **Marketing Authorisation Numbers/presentations:** Oral Solution: EU/1/01/172/003; 300 ml of solution (5 bottles of 60 ml) Cost: £307.39. Film-coated tablet 200mg/50mg: EU/1/01/172/004; 120 tablets (each pack containing 1 bottle of 120 tablets) Cost: £285.41. EU/1/01/172/005; 120 tablets (3 cartons of 5 foil blisters of 8 tablets) Cost: £285.41. EU/1/01/172/008; 120 tablets (1 carton of 10 foil blisters of 12 tablets) Cost: £285.41. Film-coated tablet 100mg/25mg EU/1/01/172/006; 60 tablets (Each pack contains 1 bottle of 60 tablets) Cost: £76.85. Further information is available on request from Abbott Laboratories Ltd., Vanwall Road, Vanwall Business Park, Maidenhead, Berkshire SL6 4XE. Date of revision of PI: May 2011. PI/79/027

Adverse events should be reported.
Reporting forms and information can be found at www.yellowcard.gov.uk
Adverse events should also be reported to Abbott on 0800 121 8267

References
1. The Antiretroviral Therapy Cohort Collaboration. Lancet 2008; 372: 293-99. **2.** Kaletra SmPC (oral and tablet formulations), available from http://www.medicines.org.uk/emc.aspx, last accessed July 2011. **3.** Murphy R et al. Seven year follow-up of a lopinavir/ritonavir (LPV/r)- based regimen in antiretroviral (ARV)-naïve subjects. 10th European AIDS Conference, November 2005; Dublin, Ireland. Poster PE7. 9/3.

Date of preparation: September 2011. AXKAL111328.

SUSTIVA® has stood the test of time. As the most widely-prescribed NNRTI therapy,* SUSTIVA®'s efficacy has empowered people with HIV to explore life's possibilities for over 10 years.[1,2]

One Tablet, Once Daily
SUSTIVA®
(efavirenz) 600 mg
film-coated tablets

*As reported in 2010; based on worldwide data for efavirenz (SUSTIVA® and Atripla) sourced from Decision Resources[1]

SUSTIVA® (efavirenz) 600mg FILM-COATED TABLETS PRESCRIBING INFORMATION
See Summary of Product Characteristics prior to prescribing
PRESENTATION: Film-coated tablets: 600mg efavirenz. **INDICATIONS:** Antiretroviral combination treatment of HIV-1 infected adults, adolescents and children 3 years of age and older. Sustiva has not been adequately studied in advanced HIV disease. **DOSAGE AND ADMINISTRATION:** Oral. Sustiva must be given in combination with other antiretroviral medications. *Adults and adolescents over 40kg:* 600mg once daily preferably at bedtime and on an empty stomach. **CONTRAINDICATIONS:** Hypersensitivity to contents. Severe hepatic impairment (Child-Pugh Grade C). Do not use in combination with St. John's wort or products that are substrates of CYP3A4. See SPC for details. **WARNINGS AND PRECAUTIONS:** Not for sole use. Discontinue use if severe rash associated with blistering, desquamation, mucosal involvement or fever develops. Advise immediate contact with doctor if experience severe depression, psychosis or suicidal ideation. Nervous system symptoms generally resolve after the first 2 - 4 weeks. Immune reactivation syndrome may arise with severe immune deficiency. Given lipodystrophy association with combination antiretroviral therapy, consider monitoring fasting serum lipids and blood glucose and manage as appropriate. Patients with hereditary disorders of galactosaemia or glucose/galactose malabsorption syndrome should not take Sustiva tablets. Patients should be advised to seek medical advice if they experience joint aches & pain, joint stiffness or difficulty in movement. Caution needed in mild to moderate liver disease or chronic Hepatitis B or C infection. Where evidence of worsening liver disease, interruption or discontinuation of treatment must be considered. Close safety monitoring is recommended in patients with severe renal failure. Caution if history of seizures. Efavirenz should not be given to patients below 3 years or who weigh less than 13kg. **DRUG INTERACTIONS:** Efavirenz is an inducer of CYP3A4 and an inhibitor of some CYP isozymes including CYP3A4. Other compounds that are substrates of CYP3A4 may have decreased plasma concentrations when co-administered with efavirenz. Efavirenz exposure may alter when given with medicinal products or foods (e.g. grapefruit) which affect CYP3A4 activity (see Contraindications above). See SPC for full drug interaction details with antiretrovirals, antimicrobials, anticonvulsants, lipid-lowering agents, antacids, warfarin, opiods, St. John's wort, antidepressants, hormonal contraceptives, calcium channel blockers, immunosuppressants, the H1-antihistamine cetirizine, lorazepam, and antifungal agents, (efavirenz dose should be reduced when co-administered with voriconazole). **PREGNANCY AND LACTATION:** Avoid use in pregnancy and lactation. Barrier contraception should always be used in combination with other methods of contraception. **UNDESIRABLE EFFECTS:** *Very common:* skin rash. *Common:* disturbance in attention, dizziness, headache, somnolence, abdominal pain, diarrhoea, nausea, vomiting, rash, pruritus, fatigue, drowsiness, problems with co-ordination and balance, abnormal dreams, anxiety, depression, insomnia. *Uncommon:* nervousness, confusion, seizures, blurred vision, vertigo, hallucinations, psychiatric adverse reactions, immune reactivation syndrome, lipodystrophy and metabolic abnormalities, osteonecrosis, acute hepatitis, acute pancreatitis. Laboratory abnormalities for liver enzymes, amylase, lipids, and false positive cannabinoid test results. *Rare:* itchy rash caused by sunlight, liver failure. *Other:* tremor, flushing, ringing noises in the ears. See SPC for full details of side effects. **LEGAL STATUS:** POM. **PACKAGE QUANTITIES AND BASIC NHS PRICE:** Blister packs of 30 tablets: £200.27. **MARKETING AUTHORISATION NUMBERS:** EU/1/99/110/009. **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, BMS House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex. UB8 1DH Telephone: 0800-731-1736. **DATE OF PI PREPARATION:** December 2010 692UK10PM107

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Bristol-Myers Squibb Pharmaceuticals Ltd Medical Information on 0800 731 1736, medical.information@bms.com

References: 1. Decision Resources. Human Immunodeficiency Virus, March 2010. **2.** SUSTIVA® Summary of Product Characteristics, November 2010. Date of preparation: April 2011 692UK11PM006

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