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Realising the benefits of HAE prophylaxis – The psychology and practicalities of adherence to long-term treatment

This is a promotional meeting that has been organised and paid for by BioCryst UK Ltd. The meeting has been endorsed by the British Society for Immunology (BSI) Clinical Immunology Professional Network (CIPN) and is for healthcare professionals only.

BIOCRYST UK WEBINAR

THURSDAY 29TH JUNE 2023 • 19:00-20:30

On behalf of BioCryst UK Ltd., we are pleased to invite you to join us for a promotional webinar, on **Thursday 29th June 2023, 19:00-20:30.**

The focus for this meeting is to discuss approaches to realising the benefits of long-term prophylaxis for patients with hereditary angioedema (HAE). The meeting will provide an update on the latest data on the long-term effectiveness of Orladeyo (berotralstat) in patients with HAE. In addition, speakers will discuss how to overcome the barriers to the uptake of long-term prophylaxis, looking at the psychology behind patient adherence and compliance, drawing upon case studies to illustrate key points and stimulate discussion.

Realising the benefits of HAE prophylaxis – The psychology and practicalities of adherence to long-term treatment
Date: Thursday 29th June 2023
Chair: Professor Stephen Jolles

AGENDA

Time	Session	Speaker
19.00	Chair's Welcome & Introduction	**Prof Stephen Jolles** *University Hospital Wales, Cardiff*
19.10	Long term effectiveness of Orladeyo	**Dr Sorena Kiani** *Consultant Immunologist, Royal Free Hospital London NHS Foundation Trust*
19.25	The psychology of patient adherence and compliance	**Prof Rob Horne** *Professor of Behavioural Science, UCL*
19.55	Patient Activation Measures: Utility in Patient Support Programmes	**Jill Stephenson** *Clinical Director at HealthNet Homecare Ltd* **Ejike Nwokoro,** *Patient Insights & Data Strategy Lead, HealthNet Homecare Ltd*
20.10	Q&A session	**All speakers. Facilitated by Prof Jolles**
20.30	Meeting Close	

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NB: Agenda subject to change

We look forward to you joining us virtually

British Society for Immunology CIPN Clinical Immunology Professional Network

bio cryst

UK.ORL.00266, May 2023

Great Britain and Northern Ireland combined prescribing information

Orladeyo▼(berotralstat) 150mg hard capsules.

Consult Summary of Product Characteristics before prescribing.

Presentation: Each hard capsule contains 150mg berotralstat (as dihydrochloride).

Indication: Routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and over.

Dosage and administration: 150mg orally once daily, at any time of day with food in patients weighing ≥40kg. Missed doses to be taken as soon as possible without exceeding one dose per day.

Contraindications: Hypersensitivity to the active substance or to any of the excipients**.**
Warnings and Precautions: Not intended for the treatment of acute HAE attacks. No clinical data available on use in patients with normal C1-INH activity. Not suitable for use in patients weighing <40kg.

Risk of QT Prolongation: ***Avoid use in:*** Patients with moderate or severe hepatic impairment due to risk of increased berotralstat concentrations, and in end stage renal disease requiring haemodialysis. Avoid use or consider ECG monitoring in patients with severe renal impairment. ***Avoid use or consider appropriate monitoring e.g. ECGs in patients with:*** known pre-existing QT prolongation or with risk factors for QT prolongation e.g. electrolyte disturbances or advancing age. ***Avoid concomitant use of:*** Drugs mainly metabolised by CYP2D6, CYP3A4 or P-gp substrates with a narrow therapeutic index or other drugs known to prolong QT (e.g. citalopram, escitalopram, amitriptyline and ondansetron). If treatment is required, consider appropriate monitoring e.g. ECG and dose adjustment of these medicines.

Interactions:

Effects of other medicines on Orladeyo: No dose adjustment is necessary for P-gp and BCRP inhibitors but close monitoring for adverse events is recommended when used with P-gp and BCRP inhibitors such as cyclosporine or grapefruit juice. Concomitant use of P-gp and BCRP inducers e.g. rifampicin, St. John's wort is not recommended due to risk of reduced efficacy.

Effects of Orladeyo on other medicines: Refer to the SmPC of concomitant medications that are mainly metabolised by CYP3A4, CYP2D6 or are P-gp substrates. Orladeyo increases concentrations of the CYP3A4 substrates midazolam, amlodipine and of the CYP2D6 substrates dextromethorphan, desipramine. Dose adjustments may be required for drugs with a narrow therapeutic index or where therapeutic monitoring is recommended e.g. CYP3A4 substrates: cyclosporine, fentanyl; CYP2D6: thioridazine, pimozide, tricyclic antidepressants and P-gp substrates: digoxin, dabigatran. Orladeyo increases tolbutamide concentrations, but no dose adjustment is required for drugs mainly metabolised by CYP2C9.

Oral contraceptives: Berotralstat may increase the concentrations of oral contraceptives metabolised by CYP3A4. There was negligible effect on CYP2C9 conversion of desogestrel to the active metabolite etonogestrel. The AUC of etonogestrel was increased, however Cmax was not affected and no dose adjustment of concomitant desogestrel is recommended

Women of childbearing potential, pregnancy and lactation:

Not recommended in women of childbearing potential unless using effective contraception, which should be continued for at least a month after the last dose of Orladeyo. Use in pregnancy not recommended due to no or limited data. Unable to exclude risk to child from excretion in breast milk therefore avoid/discontinue breast feeding or Orladeyo depending on balance of benefit to child and mother.

Undesirable effects: Please consult the SmPC for full list of side effects. Very common (≥1/10): headache, abdominal pain, diarrhoea. Common (≥1/100 to <1/10): vomiting, gastroesophageal reflux, flatulence, rash and elevations in ALT and AST. Abdominal pain and diarrhoea events were mostly reported within 1 to 3 months of initiation, were mild-moderate and resolved without specific treatment while Orladeyo was continued. Median duration of diarrhoea and abdominal pain was 3.2 and 3.5 days, respectively. LFT elevations were primarily seen in patients discontinuing androgens within 14 days of starting Orladeyo. Abrupt discontinuation of androgens immediately prior to initiation should be avoided.

Package quantities and Price: Orladeyo 150mg hard capsules 28-day blister pack £10,205 excluding VAT.

Marketing Authorisation Holder: BioCryst Ireland Limited, Block 4, Harcourt Centre, Harcourt Road, Dublin 2, D02HW77, Ireland.

Marketing Authorisation Numbers: PLGB 50680/0001, EU/1/21/1544/001 and EU/1/21/1544/002

Legal category: POM

Date of last revision of prescribing information: May 2023.

Full Prescribing Information is available from medinfoeurope@biocryst.com

UK.ORL.00268 May 2023

Adverse events should be reported. Reporting forms and information for the United Kingdom can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to BioCryst UK Ltd on +44 (0)203 8850789 or email medinfoeurope@biocryst.com