EXCELLENCE IN URTICARIA MASTERCLASS

Tuesday 7th March 2017, 08:45 – 16:15

Manchester city centre

Dr Clive Grattan (Chair – Consultant Dermatologist and Lead Clinician, Urticaria Clinic, St John's Institute of Dermatology, Guy's and St Thomas' NHS Foundation Trust, London)

Time	Session	Speaker
08:15	**Registration**	
08:50	Welcome and introduction	Dr Clive Grattan
09:00	What is CSU and when is CU not CSU?	Dr Alexander Marsland
09:40	Latest real world data on CSU	Dr Sinisa Savic
10:20	Importance of using patient reported outcomes in CSU	Dr Chris Rutkowski
11:00	**Coffee break**	
11:15	Establishing a CSU treatment pathway across several centres	Dr Runa Ali
12:00	Unusual Urticaria beyond guidelines	Dr Clive Grattan
12:45	**Lunch**	
13:30	Best practice in the management of CSU: the Irish example	Dr Lisa Devlin
14:15	**Workshop sessions:** Delegates to attend two workshops, pre-selected prior to the meeting (40min each)	
	Workshop one: Omalizumab: from guidelines to clinical practice	Dr Sinisa Savic and Ms Sarah Denman
	Workshop two: Case studies	Dr Clive Grattan
	Workshop three: Scoping the unmet psychological need in dermatology as service development	Dr Mark Turner
16:00	Panel discussion and summary	All
16:15	**Close**	

This promotional meeting is organised and funded by Novartis Pharmaceuticals Ltd.

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EXCELLENCE IN URTICARIA

UK Abbreviated Prescribing Information
Xolair® (omalizumab) 150 mg solution for injection

Indication: as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
Presentation: Pre-filled syringe of 1 ml omalizumab solution (150 mg).
Dosage and administration: Xolair treatment should be initiated by physicians experienced in the diagnosis and treatment of chronic spontaneous urticaria. The recommended dose is 300 mg by subcutaneous injection every four weeks. Injections should be administered subcutaneously by a healthcare provider into the deltoid region of the arm or, alternatively, into the thigh. Prescribers are advised to periodically reassess the need for continued therapy. Clinical trial experience of long-term treatment beyond 6 months in chronic spontaneous urticaria is limited.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Precautions: Not studied in patients with autoimmune diseases, immune-complex-mediated conditions, pre-existing renal or hepatic impairment, hyperimmunoglobulin E syndrome, allergic bronchopulmonary aspergillosis or for the prevention of anaphylactic reactions, including those provoked by food allergy, atopic dermatitis, or allergic rhinitis. Immune system disorders: Type I local or systemic allergic reactions, including anaphylaxis, may occur. Most of these reactions occurred within 2 hours after the first and subsequent injections of Xolair, but some started beyond 2 hours and even beyond 24 hours after the injection. Medicinal products for the treatment of anaphylactic reactions should always be available for immediate use following the administration of Xolair. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur. Anaphylactic reactions were rare in clinical trials. Antibodies to Xolair have been detected in a low number of patients in clinical trials. Serum sickness and serum-sickness-like reactions (delayed type III reactions) have been seen in patients treated with humanized monoclonal antibodies including omalizumab. Onset typically 1–5 days after first or subsequent injections, also after long duration of treatment. Symptoms include arthritis/arthralgias, rash, fever, lymphadenopathy. Antihistamines and corticosteroids may be useful for preventing or treating this disorder. Patients should be advised to report suspected symptoms. Parasitic (helminth) infections: IgE may be involved in the immunological response to some helminth infections. The helminth infection rate in the overall clinical programme was less than 1 in 1,000 patients. Caution may be warranted in patients at high risk of helminth infection.
Drug interactions: Based on the clearance of Xolair there is little potential for drug–drug interactions. No formal drug interaction studies have been performed. There is no pharmacological reason to expect that commonly prescribed medications used in the treatment of chronic spontaneous urticaria will interact with Xolair. In clinical studies in chronic spontaneous urticaria, Xolair was used in conjunction with antihistamines (anti-H1, anti-H2) and leukotriene receptor antagonists (LTRAs). There was no evidence that the safety of omalizumab was altered when used with these medicinal products relative to its known safety profile in allergic asthma. In addition, a population pharmacokinetic analysis showed no relevant effect of H2 antihistamines and LTRAs on omalizumab pharmacokinetics.
Undesirable effects: *Common (≥1/100 to <1/10):* sinusitis, headache, arthralgia, injection site reaction, upper respiratory tract infection. Arterial thromboembolic events (ATE): In controlled clinical trials and an observational study, a numerical imbalance of ATE was observed. In a multivariate analysis controlling for baseline cardiovascular risk factors, the hazard ratio was 1.32 (confidence interval 0.91–1.91). In an analysis of pooled clinical trials, which included all randomised, double-blind, placebo-controlled clinical trials lasting 8 or more weeks, the rate of ATE per 1,000 patient years was 2.69 (5/1,856 patient years) for Xolair-treated patients and 2.38 (4/1,680 patient years) for placebo patients (rate ratio 1.13, 95% confidence interval 0.24–5.71). Platelets: No pattern of persistent decrease in platelet counts, as observed in non-human primates, has been reported in humans. Isolated cases of idiopathic thrombocytopenia (including serious cases) have been reported in the post-marketing setting. Parasitic infections: Numerical increase in rate not statistically significant; course, severity and response to treatment unaltered. Prescribers should consult the SmPC for full information regarding other side-effects.
Quantities and basic NHS price (excl. VAT):
150 mg pre-filled syringe, £256.15.
Marketing authorisation numbers:
EU/1/05/319/008, EU/1/05/319/009 and EU/1/05/319/010.
Legal category: POM.
Date of last revision of prescribing information: March 2014 – XOL14-C039
Full prescribing information is available from: Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR. Telephone: (01276) 692255, Fax: (01276) 692508.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis (01276) 698370.