

## SECTION 1

### What is new and upcoming in the world of chronic urticaria?

M. Maurer<sup>1\*</sup>, A. M. Giménez-Arnau<sup>2</sup>, T. Zuberbier<sup>1</sup>

<sup>1</sup>Department of Dermatology and Allergy, Allergie-Centrum-Charité,  
Charité – Universitätsmedizin Berlin, Berlin, Germany

<sup>2</sup>Department of Dermatology, Hospital del Mar, Universitat Autònoma de  
Barcelona, Barcelona, Spain

#### **Corresponding author for all sections of supplement:**

Prof Ana Giménez-Arnau, Department of Dermatology, Hospital del Mar, Universitat  
Autònoma de Barcelona, Barcelona, Spain

Email: [anamariagimenezarnau@gmail.com](mailto:anamariagimenezarnau@gmail.com)

Tel +34 932 09 99 36

#### **Conflicts of interest**

- Marcus Maurer is, or was recently, a speaker and/or advisor for FAES, Almirall Hermal, Genentech, GSK, Merckle Recordati, Novartis, Sanofi-Aventis MSD, Moxie, Takeda, Shire, UCB and Uriach.
- Ana M. Giménez-Arnau has acted as a medical advisor for Uriach Pharma, Genentech and Novartis; has received research grants supported by Uriach Pharma and Novartis, and has been involved in educational activities sponsored by Uriach Pharma, Novartis, Genentech, Menarini and MSD.
- Torsten Zuberbier has acted as a consultant for Ansell, Bayer-Schering, DST, FAES, Fujisawa, HAL, Henkel, Kryolan, Leti, Menarini, Merck, MSD, Novartis, Procter & Gamble, Ranbaxy, Sanofi-Aventis, Schering Plough, Stallergenes, Takeda and UCB.

#### **Funding source**

This supplement was funded by Novartis Pharma AG. It is a publication of the Novartis supported medical education meeting that took place in Berlin in November 2015. The publication presents views of the authors and not Novartis.

**Manuscript text:** 528 words

**Figures / Tables:** 0 / 0

This supplement presents a summary of the key topics discussed during plenary sessions, workshops and debates at the second international Global Urticaria Forum, which was held in Berlin, Germany in November 2015. This interactive meeting was an excellent opportunity to present new data (both from clinical studies and real-life experience) to the medical urticaria community and to gauge opinion on remaining unmet need and unanswered questions.

Chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]), is defined as the recurrent appearance of hives, angioedema or both, without specific triggers, for 6 weeks or more.<sup>1</sup> CSU has a significant negative impact on patients' health-related quality of life as well as on society and the healthcare system.<sup>2-4</sup> New burden of illness data from the multinational, real-world ASSURE-CSU study highlight this high unmet need in terms of both the impact of disease on individual patients and the wider socioeconomic problems.<sup>3,4</sup> In order to optimize the patient journey and reduce this burden, a number of questions around management of CSU in the real-world clinical setting need to be answered.

The accurate diagnosis and classification of urticaria (using the established EAACI/GA<sup>2</sup>LEN/EDF/WAO international guideline<sup>1</sup>) is important in order to optimize treatment outcomes. Additional factors to consider when evaluating the needs of some special populations, e.g. pediatric patients, patients with angioedema but no hives and patients with chronic inducible urticaria (CIndU) are discussed, including how these factors may inform treatment decisions. Case studies from patients with diseases and syndromes that are related to chronic urticaria, but not classified as such, are also described to further explore controversies and challenges in its management. Advice is given on differing aspects of the patient journey, recent insights into the pathophysiology of urticaria and its treatment, the merits of considering the patient as a whole and the global need for data registries and specialist Urticaria Centers of Reference and Excellence.

Omalizumab has demonstrated excellent efficacy in Phase III randomized controlled trials<sup>5-8</sup> and in the real-life clinical setting<sup>9-12</sup> for the treatment of CSU patients with inadequate response to H<sub>1</sub>-antihistamines, and is well tolerated with an established safety profile. Real-life expert clinical experience with omalizumab in CSU and

important outstanding questions arising from clinical practice are discussed. The idea of a consensus algorithm for the use of omalizumab in CSU in real-life clinical practice is explored. Such a protocol could include consideration of the optimal starting dose and dosing intervals for omalizumab, how to predict response to treatment, how best to define and monitor response, when to stop treatment and whether patients can be retreated.

Despite the availability of international and national guidelines, much heterogeneity exists in the treatment of urticaria globally. Expansion of data registries such as the Chronic Urticaria Registry (CURE; [www.urticaria-registry.com](http://www.urticaria-registry.com)) and the establishment of a global network of GA<sup>2</sup>LEN Urticaria Centers of Reference and Excellence (UCAREs) over the next few years could help to harmonize diagnostic measures and treatment and to increase knowledge and promote awareness of urticaria. Attendees and readers are invited and encouraged to apply to join these global networks. In this way, they can access expertise, share knowledge and data, and ultimately help to optimize the patient journey in the management of CU.

### **Acknowledgements**

Editorial assistance was provided by Jane Blackburn and David Steele from CircleScience, an Ashfield company, part of UDG Healthcare plc. Writing support was funded by Novartis Pharma AG.

## References

1. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA<sup>2</sup>LEN/EDF/WAO Guideline for the definition, classification, diagnosis and management of Urticaria. The 2013 revision and update. *Allergy* 2014;69:868-87.
2. Maurer M, Weller K, Bindslev-Jensen C, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA<sup>2</sup>LEN task force report. *Allergy* 2011;66:317-30.
3. Weller K, Maurer M, Grattan C, et al. ASSURE-CSU: a real-world study of burden of disease in patients with symptomatic chronic spontaneous urticaria. *Clin Transl Allergy* 2015;5:29.
4. Weller K, Grattan C, Abuzakouk M, et al. Patient profile from the first international burden of illness study in inadequately controlled chronic spontaneous urticaria: ASSURE-CSU. Presented at the European Academy of Dermatology and Venereology (EADV), Copenhagen, Denmark. 7-10 October 2015 (Latebreaker ePoster LATCOP-0036). 2015.
5. Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic urticaria/chronic spontaneous urticaria who remain symptomatic on H<sub>1</sub>-antihistamines: a randomized placebo-controlled study. *J Invest Dermatol* 2015;135:67-75.
6. Kaplan A, Ledford D, Ashby M, et al. Omalizumab in patients with symptomatic chronic idiopathic/spontaneous urticaria despite standard combination therapy. *J Allergy Clin Immunol* 2013;132:101-9.
7. Maurer M, Rosén K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med* 2013;368:924-35.
8. Zhao J, Ji C, Yu W, et al. Omalizumab for the treatment of chronic spontaneous urticaria: a meta-analysis of randomized clinical trials. *J Allergy Clin Immunol* 2016;In Press.
9. Metz M, Ohanyan T, Church MK, Maurer M. Omalizumab is an effective and rapidly acting therapy in difficult-to-treat chronic urticaria: a retrospective clinical analysis. *J Dermatol Sci* 2014;73:57-62.
10. Sussman G, Hébert J, Barron C, et al. Real-life experiences with omalizumab for the treatment of chronic urticaria. *Ann Allergy Asthma Immunol* 2014;112:170-4.

11. Labrador-Horrillo M, Valero A, Velasco M, et al. Efficacy of omalizumab in chronic spontaneous urticaria refractory to conventional therapy: analysis of 110 patients in real-life practice. *Expert Opin Biol Ther* 2013;13:1225-8.
12. Rottem M, Segal R, Kivity S, et al. Omalizumab therapy for chronic spontaneous urticaria: the Israeli experience. *The Israel Medical Association journal : IMAJ* 2014;16:487-90.