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# Novartis' Xolair® confirms re-treatment efficacy in chronic spontaneous urticaria patients after treatment interruption

- *OPTIMA Phase IIIb data re-confirm that almost two thirds of patients treated with Xolair 300 mg for 6 months are well-controlled*[1]
- *Should a treatment pause be necessary, data showed almost 90% of chronic spontaneous urticaria (CSU) patients – previously well controlled – regained effective symptom control within 12 weeks of re-treatment on Xolair*[2]
- *Previous studies have shown that inadequately controlled CSU has a major impact on sleep, social lives and work*[3]

**Basel, September 16, 2017 —** Novartis, a global leader in Immunology & Dermatology, announced today new data showing almost 90% of chronic spontaneous urticaria (CSU) patients who responded well to initial Xolair® (omalizumab) treatment regained symptom control within 12 weeks of Xolair retreatment following a treatment interruption, based on Weekly Urticaria Activity Score (UAS7) criteria (UAS7≤6)[2]. Findings were presented at the 26th European Academy of Dermatology and Venereology (EADV) Congress in Geneva, Switzerland.

CSU is a distressing skin condition that appears spontaneously and causes persistent hives and/or painful deeper swelling of the skin for 6 weeks or more[4]. International treatment guidelines state that the goal of treatment for CSU is the complete elimination of symptoms[5,6]. For CSU patients who have not successfully controlled their symptoms with H1 antihistamine (H1-antagonists) treatment, Xolair can reduce or eliminate symptoms[4,7,8]. Xolair is the first and only approved therapy for CSU patients who show an inadequate response to H1 antihistamines.

"CSU can have a severe impact on quality of life. Its unpredictable nature, combined with the fact that some physicians mistakenly dismiss it as a trivial condition, can mean patients do not get adequate treatment with effective and long-term symptoms control," said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "If for some reason treatment has been interrupted, these data give patients and physicians confidence that it's possible to regain effective symptom control with Xolair."

In the OPTIMA study, 314 participants with symptoms of CSU despite taking H1 antihistamines were randomized to 24 weeks of treatment with either Xolair 150 mg or 300 mg. Individuals who responded well to this initial treatment (UAS7≤6) underwent a pause in treatment and then, if symptoms returned (UAS7>16), were retreated[2]. Symptom control (UAS7≤6) was achieved in almost 90% of retreated patients within three months[2]. Xolair was well-tolerated at both doses and during both dosing periods[2].

Further data from OPTIMA showed that, after 24 weeks of treatment, 65% of participants treated monthly with Xolair 300 mg were well-controlled (UAS7≤6) compared to 15% treated with 150 mg[2]. Between 8 and 24 weeks of treatment, 79% of patients starting on Xolair 150

mg were not well-controlled (UAS7>6) and had their dose increased to 300 mg[1]. After 3 additional doses (300 mg), 45% of these patients achieved symptom control – indicating the importance of up-dosing in some patients[1].

**About chronic urticaria and CSU**
Chronic urticaria (CU) is a severe disease that is characterized by the reoccurrence of persistent hives and/or sometimes painful deeper swelling of the skin for 6 weeks or more[4]. At any given time, the prevalence of CU is up to 1% of the world's population, and up to two thirds of these patients have CSU[6] – a form of the condition that can occur unpredictably without an identifiable trigger[6,9]. Patients with CU remain symptomatic on average for about 5 years, but in some patients, symptoms may persist for decades[10].

Although CU has a significant impact on patients' quality of life, research has highlighted that some physicians disregard the disease as a trivial condition[10,11].

**About OPTIMA**
OPTIMA is a Phase IIIb, international, multicenter, randomized, open-label, non-comparator study. A total of 314 patients with CSU experiencing symptoms despite treatment with $H_1$-antagonists were initially randomized 4:3 to Xolair 150 or 300 mg for 24 weeks in the first dosing period. Based on UAS7, patients then entered one of the following phases: step-up to 300 mg (if treated initially with 150 mg and UAS7>6 at any visit between week 8-24), or withdrawal period (if UAS7≤6), or continued treatment for 12 weeks (if treated initially with 300 mg and UAS7>6 at week 24).

**About Xolair**
Xolair is a targeted therapy that binds to immunoglobulin E (IgE). In allergic diseases and asthma, the binding of IgE by Xolair reduces symptoms by suppressing multiple cell activation mechanisms, including some that result in histamine release. Research is ongoing to understand the mechanism of action of Xolair in CSU, which could lead to a deeper understanding of how the disease develops.

Xolair is approved for the treatment of CSU in over 80 countries including the European Union and for chronic idiopathic urticaria (CIU) as it is known in the US and Canada. Xolair is approved for the treatment of moderate-to-severe or severe persistent allergic asthma in more than 90 countries, including the US since 2003 and the EU since 2005 and has over 800,000 patient years of exposure. In addition, a liquid formulation of Xolair in pre-filled syringes has been approved in the EU and 10 countries outside of the EU, including Canada and Australia. In the US, Novartis Pharmaceuticals Corporation and Genentech, Inc. work together to develop and co-promote Xolair.

**About Novartis Immunology & Dermatology**
Novartis is a global leader in Immunology & Dermatology. We are transforming the lives of people living with immunologic diseases, focusing on specialty dermatology, rheumatology, auto-inflammatory, transplant and specialty liver diseases where high unmet medical needs exist. Our leading brand Cosentyx® (secukinumab) is an innovative biologic approved in more than 70 markets for the treatment of moderate-to-severe psoriasis (PsO), ankylosing spondylitis (AS) and psoriatic arthritis (PsA). Other key brands include Xolair® (omalizumab)* in chronic spontaneous urticaria (CSU), Zortress®/Certican® and Myfortic® in transplant and Ilaris® (canakinumab), approved to treat several rare diseases including some Periodic Fever Syndromes. Our I&D pipeline includes multiple compounds in liver disease.

**In the US, Novartis Pharmaceuticals Corporation and Genentech, Inc. work together to develop and co-promote Xolair.*

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**About Novartis**
Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 119,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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