Novartis’ Xolair® recommended in new global chronic urticaria guideline

- Xolair® (omalizumab), indicated as add-on therapy for the treatment of chronic spontaneous urticaria (CSU)¹, is the only therapy recommended by the guideline for patients unresponsive to antihistamines²

- Xolair is the only licensed treatment option for CSU, a type of chronic urticaria (CU), for patients unresponsive to antihistamines¹

- The guideline aims to achieve complete symptom control of patients²

Basel, March 6, 2018 — A new global guideline on chronic urticaria (CU) recommends Xolair® (omalizumab), indicated as add-on therapy for the treatment of chronic spontaneous urticaria (CSU), for patients who are not responding to antihistamines¹. Xolair is the only licensed treatment option for CSU, a type of CU, for patients unresponsive to antihistamines¹.

CU, including CSU, is a severe disease that causes itchy, persistent hives and painful swelling. The guideline recommends Xolair as the only treatment qualified with very good efficacy and very good safety in CSU². The guideline was endorsed by key dermatologic and allergy professional medical societies around the world.

Marcus Maurer, MD, Professor of Dermatology and Allergy and Director of Research at the Department of Dermatology and Allergy, Allergie-Centrum-Charité of the Charité - Universitätsmedizin in Berlin, Germany said: "I highly welcome the new guideline, as it brings greater public awareness of the disease and treatment. Also, it provides clear directions for physicians on how to treat patients suffering from this undertreated, debilitating disease. The most important phrase is: Treat the disease until it is gone."

“This guideline is encouraging news for CSU patients who have difficult to control symptoms,” said Shreeram Aradhye MD, Chief Medical Officer and Global Head Medical Affairs, Novartis Pharmaceuticals. “The recommendation reinforces the important role of Xolair to provide effective symptom control in CSU when antihistamines prove inadequate. Xolair is the only biologic shown to be effective in CSU.”

The new guideline aims to achieve complete symptom control of patients. Studies have shown that CSU, if not controlled, or only partially controlled, has a major impact on the quality of sleep and the social and working lives of patients³⁴. Patients treated with Xolair for 12 weeks experienced significant improvements in quality of life by 78% (vs placebo 44%, p<0.0001) as measured by the Dermatology Life Quality Index (DLQI)⁵. In addition, data show that almost 90% of CSU patients who responded well to initial Xolair treatment regained symptom control within 12 weeks of Xolair retreatment following a treatment interruption, based on Weekly Urticaria Activity Score (UAS7) criteria (UAS7≤6)⁶. Xolair is currently only licensed for CSU¹. Also, Xolair is approved for the treatment of moderate-to-severe or severe persistent allergic asthma¹.
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\(^7\). 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\(^8\) – a form of the condition that can occur unpredictably without an identifiable trigger\(^8,9\). Patients with CU remain symptomatic on average for about 5 years, but in some patients, symptoms may persist for decades\(^7\). Although CU has a significant impact on patients' quality of life, research has highlighted that some physicians disregard the disease as a trivial condition\(^7,10\).

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 better 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\(^\text{®}\) (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\(^\text{®}\) (omalizumab) in chronic spontaneous urticaria (CSU), Zortress\(^\text{®}/\text{Certican}\(^\text{®}\) (everolimus) and Myfortic\(^\text{®}\) (mycophenolic acid) in transplant and Ilaris\(^\text{®}\) (canakinumab), approved to treat several rare diseases including some Periodic Fever Syndromes. Our I&D pipeline includes multiple compounds in liver disease.

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uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 122,000 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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References
3. Maurer M et al. The burden of chronic spontaneous urticaria is substantial: Real-world evidence from ASSURE-CSU. Allergy 2017. Advanced online publication. DOI:10.111
5. Rosén K et al. Chronic idiopathic/spontaneous urticaria (CIU/CSU) refractory to standard of care: omalizumab improves quality of life (QoL) as assessed by the dermatology life quality index. 23rd World Congress of Dermatology, Vancouver, Canada, 2015. Oral presentation (presentation number FC23-06).

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Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Friedrich von Heyl
Novartis Global Pharma Communications
+41 61 324 8984 (direct)
+41 79 749 0286 (mobile)
friedrich.vonheyl@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417