Novartis’ Xolair® recommended in new global chronic urticaria guideline

- Xolair® (omalizumab), indicated as add-on therapy for the treatment of chronic spontaneous urticaria (CSU), is the only therapy recommended by the guideline for patients unresponsive to antihistamines.
- Xolair is the only licensed treatment option for CSU, a type of chronic urticaria (CU), for patients unresponsive to antihistamines.
- The guideline aims to achieve complete symptom control of patients.

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

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 CSU. 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 Aradhya 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 patients. 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). 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 (UA7) criteria (UA7≤6). Xolair is currently only licensed for CSU. Also, Xolair is approved for the treatment of moderate-to-severe or severe persistent allergic asthma.
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\(^\text{®}\)/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.

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