

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis receives European Commission approval for self-administration of Xolair® across all indications**

- The EC approval underscores the long-term safety and efficacy of Xolair demonstrated in clinical studies and by 13 years of real-world use in Europe¹
- Xolair® (omalizumab) prefilled syringe (PFS) is the first and only biologic to receive European Commission (EC) approval for self-administration in severe allergic asthma (SAA) and chronic spontaneous urticaria (CSU)
- Novartis is reimagining care in SAA and CSU by providing patients the flexibility to fit their treatment around their lives

Basel, Switzerland, December 13, 2018 – Novartis today announced that the European Commission (EC) has approved Xolair® (omalizumab) prefilled syringe (PFS) for self-administration, allowing patients with severe allergic asthma (SAA) and chronic spontaneous urticaria (CSU) to administer their own treatment. With this approval, Xolair is the first and only biologic to offer the option of self-administration for SAA and CSU.

Xolair, which targets immunoglobulin E (IgE), is the first and only biologic to be approved in the European Union, Iceland, Norway, and Liechtenstein for self-administration (or administration by a trained caregiver) for the treatment of SAA in patients 6 years of age and older that have difficulty in controlling their asthma symptoms and for CSU in patients 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. Studies in severe allergic asthma and chronic spontaneous urticaria have shown that appropriately trained patients can effectively self-administer Xolair at home¹⁻³.

The efficacy of Xolair has been demonstrated in large-scale clinical trials and real world studies. Xolair has been shown to reduce severe exacerbations and corticosteroid use in SAA¹, as well as rapidly reduce symptoms in CSU⁴.

The EC approval will allow patients with no known history of anaphylaxis to self-inject Xolair PFS, or be injected by a trained lay-caregiver, from the fourth dose onwards, if a physician determines that this is appropriate⁵. The patient or the caregiver must have been trained in the correct sub-cutaneous injection technique and the recognition of the early signs and symptoms of serious allergic reactions⁵.

“Today’s positive news is a big step forward for patients living with immunoglobulin E-mediated asthma and chronic spontaneous urticaria. Decreasing the number of regular clinic visits allows patients the flexibility to fit their treatment around their lives and helps to reduce the burden of these diseases. It also allows physicians a greater capacity for patients who need extra care, which is important” said Professor Dr. Karl-Christian Bergmann, Allergy Center Charité, Berlin.

Administered via injection every two or four weeks, Xolair is widely used and well tolerated⁶. With 13 years of physician experience in Europe and one million patient years of exposure, use of Xolair in SAA and CSU is supported by a wealth of evidence from randomized clinical trials and real-world studies¹⁻³. Anaphylactic reactions were rare in clinical trials ($\geq 1/10,000$ to $< 1/1,000$)⁵ and via post-marketing reports (approximately 0.2 percent)⁵.

About Allergic Asthma and Chronic Spontaneous Urticaria

Asthma is a serious and chronic lung disease affecting an estimated 235 million people around the world⁷. It causes swelling and narrowing of the airways, making breathing difficult⁷. Allergic asthma, the most common form of asthma, accounts for approximately 60 percent of asthma cases^{8,9}.

Urticaria is a severe disease characterized by persistent hives and/or painful deeper swelling of the skin tissue (angioedema). When this persists for 6 weeks or more, it is classified as chronic urticaria¹⁰. Chronic spontaneous urticaria (CSU), also called chronic idiopathic urticaria (CIU), is identified as the appearance of hives and/or angioedema without an identifiable trigger for more than 6 weeks¹⁰. Most patients with CSU remain symptomatic for more than one year, but in some patients, symptoms may persist for decades¹⁰.

About Xolair

Xolair (omalizumab) is the only approved antibody designed to target and block immunoglobulin E (IgE). By reducing free IgE, down-regulating high-affinity IgE receptors and limiting mast cell degranulation, Xolair minimizes the release of mediators throughout the allergic inflammatory cascade.

As an injectable prescription medicine, 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. 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 has over one million patient years of exposure. In addition, a liquid formulation of Xolair in pre-filled syringes has been approved in the EU and more than 10 countries outside of the EU, including Canada, the US, and Australia. In the US, Novartis and Genentech, Inc. work together to develop and co-promote Xolair. Outside the US, Novartis markets Xolair and records all sales and related costs.

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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 is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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