

## MEDIA UPDATE

# Novartis receives EC approval for new Xolair<sup>®</sup> indication to treat severe chronic rhinosinusitis with nasal polyps

- *EC approves Xolair<sup>®</sup> (omalizumab) as an add-on therapy for severe chronic rhinosinusitis with nasal polyps, the first anti-immunoglobulin E antibody approved in this indication<sup>1</sup>*
- *Chronic rhinosinusitis with nasal polyps is a debilitating condition for many patients, with symptoms including nasal blockage, difficulty breathing and sleeping, and loss of sense of smell, which reduce quality of life<sup>2-4</sup>*
- *Approval builds on well-established efficacy and safety record of Xolair, which has over 1.3 million patient years of exposure and unparalleled real-world evidence in severe allergic asthma and chronic spontaneous urticaria<sup>5</sup>*

**Basel, August 6, 2020** — Novartis today announced that the European Commission (EC) has approved Xolair<sup>®</sup> (omalizumab) as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with INC does not provide adequate disease control<sup>1</sup>. Phase III studies have shown that Xolair reduces nasal polyp size (defined by Nasal Polyp Score; NPS) and improves symptoms and quality of life in patients with CRSwNP<sup>5</sup>. Xolair is the first treatment for CRSwNP specifically targeting and blocking immunoglobulin E (IgE), a key driver in the inflammatory pathway of this disease.

“People with chronic rhinosinusitis with nasal polyps can experience significant quality of life impairment as a result of their symptoms. The symptoms include long-term nasal congestion and blockage, sleep disruption and loss of smell and taste,” said Lars Ingemann, Academic Director, EUFOREA\*. “The EUFOREA\* patient advisory board welcomes today’s approval, which will provide an additional treatment option to patients with severe chronic rhinosinusitis with nasal polyps.”

\*EUFOREA: The European Forum for Research and Education in Allergy and Airway Diseases

### **About Xolair<sup>®</sup> (omalizumab)**

Xolair is the only approved anti-immunoglobulin E (IgE) antibody treatment specifically designed to target and block 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.

An injectable prescription medicine, Xolair is approved for the treatment of moderate-to-severe or severe persistent allergic asthma in more than 100 countries, including the US since 2003 and the EU since 2005. Xolair is approved for the treatment of chronic spontaneous urticaria in over 90 countries including the EU and for chronic idiopathic urticaria (CIU), as it is known in the US and Canada. Xolair has over 1.3 million patient years of exposure. In addition, a liquid formulation of Xolair in pre-filled syringes has been approved in the EU and in more than 20 countries outside of the EU, including Canada, the US and Australia. The self-administration indication for Xolair in pre-filled syringes was also approved in the EU in 2018, and has since been approved in several other countries, including Australia, Taiwan, Argentina and Brazil. In the US, Novartis and Genentech, Inc. work together to develop and co-promote Xolair. Outside of the US, Novartis markets Xolair and records all sales and related costs.

For chronic rhinosinusitis with nasal polyps (CRSwNP), Xolair is indicated in the EU as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe CRSwNP for whom therapy with INC does not provide adequate disease control<sup>1</sup>.

### **About Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

Chronic rhinosinusitis with nasal polyps (CRSwNP) impacts up to 4% of people worldwide. It is a potentially debilitating condition in adults that is characterized by inflammation of the nose and paranasal sinuses with the presence of benign inflammatory polyps (nasal polyps) on the lining of the nasal sinuses or nasal cavity, which can block normal airflow<sup>2-4</sup>. It is possible to have a single polyp or several, and the size of the polyps can vary from microscopic to several centimeters<sup>6,7</sup>.

Symptoms can include nasal blockage/obstruction, nasal congestion, nasal discharge, facial pain/pressure and reduction in, or loss of, sense of smell<sup>2,3</sup>. CRSwNP is diagnosed by a physical examination with endoscopy. The condition can be associated with asthma, cystic fibrosis and aspirin sensitivity<sup>8</sup>. It is also associated with significant morbidity and decreased health-related quality of life, with quality of life impairment<sup>9-14</sup>. Patients with CRSwNP experience significantly lower health-related quality of life than the general population, with a greater impact for patients with more severe disease, other conditions (comorbidities) or whose CRSwNP has not responded to treatment (refractory disease)<sup>12</sup>.

Currently, after standard of care intranasal corticosteroids (INC), surgery and systemic corticosteroids are the main treatments for this disease all over the world. Many patients choose them; however, they are often not effective in controlling chronic symptoms over time, due to nasal polyp regrowth. After sinus surgery, nasal polyps recur in up to 80% of people, with approximately 40% requiring at least one additional surgery<sup>9</sup>. Approximately 80% of people remain uncontrolled 3–5 years after sinus surgery<sup>15</sup>.

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### 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 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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