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## **Xolair® (omalizumab) significantly reduced nasal polyps and congestion symptoms in adults with chronic rhinosinusitis with nasal polyps in two phase III studies**

- *In the phase III POLYP 1 and POLYP 2 studies, omalizumab met both co-primary endpoints and key secondary endpoints in adults with chronic rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to intranasal corticosteroids<sup>1</sup>*
- *Omalizumab demonstrated a safety profile consistent with previous research for approved conditions of chronic spontaneous urticaria and severe allergic asthma<sup>1</sup>*
- *CRSwNP impacts up to 4 percent of people worldwide, and the prevalence increases with age<sup>2</sup>*

**Basel, June 3, 2019** – Novartis today announced positive topline data from two phase III, multicenter studies evaluating omalizumab (Xolair®) for the treatment of adults with chronic rhinosinusitis with nasal polyps (CRSwNP) who have not adequately responded to standard-of-care (intranasal corticosteroids). Omalizumab, an injectable biologic treatment designed to target and block immunoglobulin E (IgE), met both co-primary endpoints and key secondary endpoints across both POLYP 1 and POLYP 2 phase III trials<sup>1</sup>.

CRSwNP is the inflammation of the nose and paranasal sinuses with the presence of nasal polyps on the lining of the nasal sinuses or nasal cavity<sup>3,4,5</sup>.

The co-primary endpoints of POLYP 1 and POLYP 2 were change from baseline in Nasal Polyp Score (NPS) and change from baseline in average daily Nasal Congestion Score (NCS) over 24 weeks<sup>6,7</sup>. Omalizumab demonstrated statistically significant and clinically relevant improvements in both of these co-primary outcomes<sup>1</sup>. Key secondary endpoints met include Sino-nasal Outcome Test-22 (SNOT-22) for health-related quality of life (HRQoL), the University of Pennsylvania Smell Identification Test (UPSIT) for sense of smell, posterior and anterior rhinorrhea scores for post-nasal drip and runny nose respectively<sup>1</sup>.

“We are very pleased with the initial outcomes from the POLYP 1 and POLYP 2 trials. This is an important and exciting milestone for Xolair, which continues to help thousands of people around the world with severe allergic asthma and chronic spontaneous urticaria,” said John Tsai, Head of Global Drug Development and Chief Medical Officer, Novartis. “The results from these pivotal studies provide further evidence of the role of IgE in several inflammatory and respiratory conditions. Xolair reduces the amount of free IgE and in this study substantially reduced the size of nasal polyps and associated symptoms that impact the quality of life for patients with chronic rhinosinusitis with nasal polyps.”

In the studies, omalizumab was generally well tolerated with overall adverse events rates comparable to those observed in previous phase III trials in patients with moderate and severe allergic asthma and chronic spontaneous urticaria<sup>1</sup>.

“Although the disease is not visible, people with nasal polyps may have significantly impaired quality of life – especially those with asthma who have increased nasal obstruction and loss sense of smell, which can impact them physically, socially and mentally,” said Professor Claus Bachert, Upper Airways Research Laboratory, Clinics ENT-Department, University Hospital Ghent, Belgium. “The results of these studies are an important step forward to improving the lives of these patients.”

Additional findings and detailed results of co-primary and secondary endpoints from these trials will be presented at an upcoming scientific congress.

#### **About Xolair® (omalizumab)**

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.

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 chronic spontaneous urticaria 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. The self-administration indication for Xolair in pre-filled syringes was also approved in the EU in 2018. 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.

Xolair is being investigated for the treatment of adults with chronic rhinosinusitis with nasal polyps (CRSwNP) but is not approved in this indication anywhere in the world.

#### **About POLYP 1 and POLYP 2**

POLYP 1 and POLYP 2 are replicate phase III studies designed to determine the efficacy and safety of omalizumab compared with placebo in adult patients with CRSwNP who have had an inadequate response to standard-of-care treatment. Both trials were randomized, multicenter, double-blind and placebo-controlled. POLYP 1 involved 138 patients and POLYP 2 involved 127 patients, with and without a history of surgery. The primary outcomes for both trials were change from baseline in average daily nasal congestion score at Week 24, and change from baseline in nasal polyp score to week 24. Patients in the studies were administered either omalizumab or placebo by subcutaneous injection every two to four weeks<sup>6,7</sup>.

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

Chronic rhinosinusitis with nasal polyps (CRSwNP) is the inflammation of the nose and paranasal sinuses with the presence of noncancerous lesions (nasal polyps) on the lining of the nasal sinuses or nasal cavity<sup>3,4,5</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>8,9</sup>. Symptoms can include nasal blockage/obstruction, nasal congestion, nasal discharge, facial pain/pressure and reduction in or loss of smell<sup>4</sup>. CRSwNP is diagnosed by physical examination with endoscopy. The condition can be associated with asthma, cystic fibrosis and aspirin sensitivity<sup>10</sup>.

#### **About Novartis in Respiratory**

Novartis is a leading respiratory company that drives novel advances to improve the lives of those living with lung conditions around the world. Through courageous innovation and close partnership with patients and medical experts, Novartis is committed to solving the unmet

needs in the respiratory arena including asthma, chronic obstructive pulmonary disease (COPD), chronic spontaneous urticaria and nasal polypsis.

### **Disclaimer**

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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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 105 000 people of more than 140 nationalities work at Novartis around the world. Find out more at [www.novartis.com](http://www.novartis.com).

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