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Novartis announces FDA filing acceptance of Xolair® (omalizumab) for treatment of nasal polyps

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- The submission is based on positive results from the Phase III POLYP 1 and POLYP 2 studies of Xolair in adults with chronic rhinosinusitis with nasal polyps with inadequate response to intranasal corticosteroids
- If approved, Xolair would become the first antibody to help reduce the size of nasal polyps and help improve symptoms through targeting and blocking immunoglobulin E
- Frequently co-occurring with other respiratory conditions, nasal polyps is a chronic condition and causes a range of symptoms impacting patients' lives including loss of sense of smell and nasal congestion[1]

Novartis today announced that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) for Xolair® (omalizumab) for the treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to intranasal corticosteroids. If approved, Xolair would become the first antibody to help reduce the size of nasal polyps and help improve symptoms through targeting and blocking immunoglobulin E (IgE). The FDA is expected to make a decision on approval for this indication by Q3 2020.

"With millions of Americans living with this serious respiratory condition, there is a significant unmet need for additional treatment options for patients who do not respond to intranasal corticosteroids," said Victor Bultó, President, Novartis Pharmaceuticals Corporation. "The FDA's acceptance of this sBLA is an important step on our path to continually reimagining medicine and understanding the full potential of Xolair across allergic, respiratory and inflammatory conditions and associated comorbidities."

Nasal polyps is a common and potentially debilitating condition in adults, impacting 13 million people in the US[2,3]. Currently, there are limited treatment options available and many patients opt for nasal surgery or systemic steroids, which often cannot effectively control symptoms over time due to nasal polyps regrowth. Nasal polyps presents as noncancerous lesions on the lining of the nasal sinuses or nasal cavity associated with irritation and inflammation, which can block normal airflow[1]. Frequently co-occurring with other respiratory conditions, nasal polyps impacts approximately 45 percent of people with adult-onset asthma and approximately 30 of percent people with chronic rhinosinusitis, resulting in chronic rhinosinusitis with nasal polyps (CRSwNP) if the nasal polyps and sinusitis symptoms are present for 12 weeks or longer[1,4]. After sinus surgery, nasal polyps recurs in up to 80 percent of people, with approximately 40 percent requiring at least one further surgery[5].

This sBLA is based on results from the Phase III POLYP 1 and POLYP 2 trials, which showed Xolair met both co-primary and multiple secondary endpoints in treating adult patients with CRSwNP who have not adequately responded to intranasal corticosteroids. The co-primary endpoints were change from baseline in Nasal Polyp Score (NPS) and change from baseline in average daily Nasal Congestion Score (NCS) at 24 weeks. Key secondary endpoints that were met included improvement in the Sino-Nasal Outcome Test-22 (SNOT-22) health-related quality of life assessment, improvement in sense of smell, post-nasal drip (posterior rhinorrhea), and runny nose (anterior rhinorrhea). The safety profile in these trials were consistent with the known safety profile for Xolair, with no new unexpected safety signals identified. Full results from the POLYP 1 and POLYP 2 studies were recently presented during an oral session at the 2019 American College of Allergy, Asthma and Immunology (ACAAI) Annual Meeting (abstract #D450).

Xolair is an injectable biologic medicine designed to target and block IgE. Xolair is currently approved for the treatment of moderate to severe persistent allergic asthma in people six years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids, and for chronic idiopathic urticaria (CIU) in people 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. In the US, Novartis Pharmaceuticals Corporation and Genentech work together to develop and co-promote Xolair.

In November 2019, Novartis submitted to the European Medicines Agency a Type II variation application for Xolair for the treatment of nasal polyps. A decision is expected in 2020.

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 intranasal corticosteroids. Both trials were randomized, multicenter, double-blind and placebo-controlled. POLYP 1 involved 138 patients, and POLYP 2 involved 127 patients. The co-primary outcomes for both trials were change from baseline to week 24 in average daily Nasal Congestion Score and Nasal Polyp Score. Patients in the studies were administered either omalizumab or placebo by subcutaneous injection every two to four weeks in addition to background intranasal corticosteroid[6,7].

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. Outside the US, Novartis markets Xolair and records all sales and related costs.

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 alliances with patients and medical experts, Novartis is committed to solving the unmet needs in asthma management and improving better treatment outcomes for chronic obstructive pulmonary disease (COPD).

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the 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 and requirements for increased pricing transparency; 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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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