Novartis Announces FDA Approval of Xolair® (omalizumab) for Chronic Idiopathic Urticaria (CIU), a Form of Chronic Hives

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- - First-in-class medicine approved for CIU, a burdensome skin condition that can cause hives, severe itch, and swelling that can last many months and years
- - Xolair® is approved for CIU patients age 12 years and older who remain symptomatic despite H1-antihistamine treatment, the only previously FDA-approved therapy for CIU
- - In clinical studies, Xolair 300 mg and 150 mg significantly improved primary efficacy measure of Itch Severity Score compared to placebo

EAST HANOVER, N.J., March 21, 2014 /PRNewswire/ -- Novartis today announced that the US Food and Drug Administration (FDA) approved Xolair® (omalizumab) for the treatment of chronic idiopathic urticaria (CIU), a form of chronic hives. The new use is for patients 12 years of age and older who remain symptomatic despite treatment with H_1-antihistamine therapy. Xolair is not used to treat other forms of urticaria (hives) and is not for use in children less than 12 years of age. Xolair is jointly developed by Genentech and Novartis Pharma AG and is co-promoted by Novartis Pharmaceuticals Corporation with Genentech in the United States.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/59692-novartis-announces-fda-approval-xolair-chronic-idiopathic-urticaria-ciu

CIU is characterized by hives that spontaneously occur without an identifiable cause and reoccur for six weeks or more. CIU symptoms include red, swollen, itchy and sometimes painful hives on the skin that can be burdensome and last for many months and even years. Nearly 50% of these patients remain symptomatic despite treatment with approved doses of H_1-antihistamines, the only previously FDA-approved therapy for CIU. In the US, it is estimated that approximately 1.5 million people suffer from CIU. Women are twice as likely as men to experience CIU and most people develop symptoms between the ages of 20 and 40 years.

"For CIU patients, it can take months or even years to get the right diagnosis and some relief," said Andre Wyss, President, Novartis Pharmaceuticals Corporation, and President, Novartis Corporation. "Novartis is proud to have collaborated with clinicians to bring forward a new treatment option for those who suffer from this serious skin condition. This is part of our quest to deliver innovative medicines that address unmet need."

"CIU can be a frustrating condition for patients," said Mike Tringale, senior vice president at the Asthma and Allergy Foundation of America (AAFA). "This new use for Xolair gives hope to appropriate patients who can go for months or even years without getting satisfactory itch and hive reduction."

Xolair is the first medicine approved by the FDA for CIU since H_1-antihistamines.

The clinical profile of Xolair for the treatment of CIU was evaluated in two studies called ASTERIA I and ASTERIA II. In these studies, 641 patients 12 to 75 years old received subcutaneous injections of Xolair at 75 mg, 150 mg, 300 mg, or placebo. Xolair or placebo was given every four weeks for 24 weeks (ASTERIA I) and

12 weeks (ASTERIA II). In addition, patients continued to receive the H_1-antihistamine treatment they had been taking for CIU before starting treatment with Xolair.

Efficacy and Safety Findings
The efficacy of Xolair in patients 12 years and older who remained symptomatic despite approved doses of H_1-antihistamine treatment was assessed in two Phase III studies, ASTERIA I and II. The studies used scales known as the average (mean) weekly Itch Severity Score (ISS) and the weekly hive count score, where potential scores ranged from 0 to 21 for both scales. Xolair 300 mg and 150 mg met the primary endpoint across these studies, which showed Xolair significantly improved the Itch Severity Score. In addition, Xolair 300 mg and 150 mg significantly decreased the weekly hive count score. In many cases, patients reported no itch or hives at week 12.

In ASTERIA I, Xolair 150 mg improved ISS from the starting measurement by a reduction of 6.7 (47%) and Xolair 300 mg improved ISS from the starting measurement by a reduction of 9.4 (66%) at Week 12, compared to a reduction of 3.6 (25%) score improvement for patients who received placebo. Also, a larger proportion of patients (36%) treated with Xolair 300 mg reported no itch and no hives at Week 12, compared to patients treated with Xolair 150 mg (15%), and patients in the placebo group (9%). Similar results were observed for the ASTERIA II study. The 75-mg dose did not demonstrate consistent evidence of efficacy and is not approved for use.

The most common side effects in patients treated with Xolair were nausea, headaches, swelling of the inside of the nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.

Xolair in Allergic Asthma
Xolair was originally approved in the US in 2003 for people 12 years and older with moderate to severe persistent allergic asthma caused by year-round allergens in the air and not controlled by asthma medicines called inhaled steroids. Xolair should not be used to treat other allergic conditions. Xolair is not a rescue medicine and should not be used to treat sudden asthma attacks. Xolair should not be used in children under 12 years of age.

Please visit http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/Xolair.pdf for Xolair full Prescribing Information, as received from the US FDA on March 21, 2014.

About Xolair
Xolair® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat adults and children 12 years of age and older with:

- moderate to severe persistent allergic asthma who have had a skin or blood test that is positive for allergic asthma and whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids.
- chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H_1-antihistamine treatment.

Xolair is not used to treat other allergic conditions, other forms of urticaria (hives), acute bronchospasm (serious and sudden breathing problems) or status asthmaticus (acute, severe prolonged asthma attack that can be life-threatening).
Xolair is not for use in children less than 12 years of age.

IMPORTANT SAFETY INFORMATION
A severe allergic reaction called anaphylaxis can happen when a patient receives Xolair. The reaction can occur after the first dose, or after many doses. It may also occur right after a Xolair injection or days later.

Anaphylaxis is a life-threatening condition and can lead to death. Patients must go to the nearest emergency room right away if they have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of "impending doom"
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

The patient's healthcare provider will monitor the patient closely for symptoms of an allergic reaction while they are receiving Xolair and for a period of time after the patient's injection. The patient's healthcare provider should talk to the patient about getting medical treatment if they have symptoms of an allergic reaction after leaving the healthcare provider's office or treatment center.

Patients must not receive Xolair if they are allergic to omalizumab or any of the ingredients in Xolair.

Before receiving Xolair, patients must tell their healthcare provider about all of their medical conditions, including if they:

- have any other allergies (such as food allergy or seasonal allergies)
- have sudden breathing problems (bronchospasm)
- have or have had low white blood cell count (patients should ask their doctor if they are not sure)
- have or have had a parasitic infection
- have or have had cancer
- are pregnant or plan to become pregnant. It is not known if Xolair may harm a patient's unborn baby.
- if a patient becomes pregnant while taking Xolair, they should talk to their healthcare provider about registering with the Xolair Pregnancy Registry. Patients can get more information and register by calling 866 4XOLAIR (866-496-5247) or visit http://www.xolairpregnancyregistry.com.
- are breastfeeding or plan to breastfeed. It is not known if Xolair passes into breast milk.

Patients must tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

Receiving Xolair

- Xolair should be given by a healthcare provider in a healthcare setting.
- Xolair is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.
- The patient's healthcare provider may do certain tests and change the patient's Xolair dose as needed.
- Patients must not stop taking any of their other asthma or hive medicine unless their healthcare providers tell them to.
- Patients may not see improvement in their symptoms right away after Xolair treatment.

Possible side effects of Xolair
Xolair may cause serious side effects, including:

- See "What is the most important information I should know about Xolair?" in the Xolair Medication Guide at http://www.xolair.com
- Cancer. People who receive treatment with Xolair may have a higher chance for getting certain types of cancer.
- Fever, muscle aches, and rash. Some people who take Xolair get these symptoms 1 to 5 days after receiving a Xolair injection. If a patient has any of these symptoms, they must tell their healthcare provider.

- Parasitic infection. Some people who are at a high risk for parasite (worm) infections, get a parasite infection after receiving Xolair. The patient's healthcare provider can test the patient's stool to check if they have a parasite infection.
- High blood levels of a certain antibody (Serum total IgE)

The most common side effects of Xolair:

- In people with allergic asthma: pain especially in the arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of the ears.
- In people with chronic idiopathic urticaria: nausea, headaches, swelling of the inside of the nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.

These are not all the possible side effects of Xolair. Patients should call their doctor for medical advice about side effects.

Report side effects to the FDA at (800) FDA-1088 or http://www.fda.gov/medwatch. Report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

Please see full Prescribing Information, including Medication Guide for additional important safety information at http://www.xolair.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "can," "remain," "quest," "hope," "potential," "may," "must," "will," "should," or by express or implied discussions regarding new indications or labeling for Xolair, or regarding potential future revenues from Xolair. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Xolair will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Xolair will achieve any particular levels of revenue in the future. In particular, management's expectations regarding these products could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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 Pharmaceuticals Corporation researches, develops, manufactures and markets innovative medicines aimed at improving patients' lives. We offer a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 136,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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