Novartis receives FDA approval of Xolair® (omalizumab) self-injection with prefilled syringe across all indications for appropriate patients

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- Xolair for self-injection offers healthcare providers and appropriate patients another administration option for more flexibility in managing their treatment

EAST HANOVER, N.J., April 12, 2021 -- Novartis today announced that the US Food and Drug Administration (FDA) approved the supplemental Biologics License Application for Xolair® (omalizumab) prefilled syringe for self-injection in appropriate patients across all approved US indications.[1] Xolair is the only FDA-approved biologic designed to target and block immunoglobulin E (IgE) for the treatment of moderate to severe persistent allergic asthma, chronic idiopathic urticaria (CIU) and nasal polyps.

"Today's FDA approval represents an important milestone for Xolair and highlights our continued commitment to innovation for patients since its first approval in 2003," said Victor Bultó, President, Novartis Pharmaceuticals Corporation. "With the new offering of self-injection for Xolair, healthcare providers now have an additional administration option for appropriate patients, which is particularly timely given the COVID-19 pandemic."

Before starting self-injection with Xolair prefilled syringe, the patient must have no prior history of anaphylaxis and be closely observed by a healthcare provider for at least three injections with no hypersensitivity (allergic reactions). After Xolair therapy has been initiated and safely established in a healthcare setting, a healthcare provider may determine whether self-injection with Xolair pre-filled syringe by the patient or caregiver is appropriate. The healthcare provider must train the patient or caregiver on the correct subcutaneous injection technique, how to recognize the signs and symptoms of anaphylaxis and how to treat anaphylaxis appropriately, before the first self-injection outside a healthcare setting.

"Expanding treatment options for personalized care and self-management is always welcome news for the patient community," said Kenneth Mendez, CEO and President, Asthma and Allergy Foundation of America. "The possibility of administering FDA-approved treatment outside of the healthcare provider's office, but still guided by that healthcare provider, may reduce barriers to care for patients and their caregivers."

Approximately 460,000 patients have been treated in the US with Xolair since its initial approval in 2003.[2] The use of Xolair across allergic asthma, CIU and nasal polyps is based on a well-established efficacy and safety profile which is supported by a robust clinical development program, including 10 Phase III studies.

In the US, Novartis Pharmaceuticals Corporation and Genentech, a member of the Roche Group, work together to develop and co-promote Xolair.

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 prefilled syringes has been approved in the US, EU and more than 10 countries outside of the EU, including Canada and Australia. The self-administration indication for Xolair in prefilled syringes was also approved in the EU in 2018. Outside the US, Novartis markets Xolair and records all sales and related costs.

Xolair US Indications

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat:

- moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if people have allergies to year-round allergens. It is not known if XOLAIR is safe and effective in people with asthma under 6 years of age.
- nasal polyps in people 18 years of age and older when medicines to treat nasal polyps called nasal corticosteroids have not worked well enough. It is not known if XOLAIR is safe and effective in people with nasal polyps under 18 years of age.
- chronic idiopathic urticaria (CIU, chronic hives without a known cause) in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if XOLAIR is safe and effective in people with CIU under 12 years of age.

XOLAIR is not used to treat other allergic conditions, other forms of hives, or sudden breathing problems.

IMPORTANT SAFETY INFORMATION

What is the most important information patients should know about XOLAIR?

Severe allergic reaction. 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 treatment is initiated. The patient's healthcare provider should talk to the patient about getting medical treatment if they have symptoms of an allergic reaction.

Patients should not receive and use XOLAIR if they are allergic to omalizumab or any of the ingredients in XOLAIR.

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

- have a latex allergy or any other allergies (such as food allergy or seasonal allergies). The needle cap on the XOLAIR prefilled syringe contains a type of natural rubber latex
- have sudden breathing problems (bronchospasm)
- have ever had a severe allergic reaction called anaphylaxis
- 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
- are breastfeeding or plan to breastfeed. It is not known if XOLAIR passes into breast milk. Patients should talk with their healthcare provider about the best way to feed their baby while they receive and use XOLAIR.

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

How should patients receive and use XOLAIR?

- When starting treatment XOLAIR should be given by a healthcare provider in a healthcare setting.
- If a healthcare provider decides that a patient or a caregiver may be able to give their own XOLAIR prefilled syringe injections, they should receive training on the right way to prepare and inject XOLAIR.
- Do not try to inject XOLAIR until a patient has been shown the right way to give XOLAIR prefilled syringe injections by a healthcare provider. Use XOLAIR exactly as prescribed by a healthcare provider. For children 12 years of age and older, XOLAIR prefilled syringe may be self-injected under adult supervision. For children 6 to 11 years of age, XOLAIR prefilled syringe should be injected by a caregiver.
- See the detailed Instructions for Use that comes with XOLAIR for information on the right way to prepare and inject XOLAIR.
- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.
- In people with asthma and nasal polyps, a blood test for a substance called IgE must be performed before starting XOLAIR to determine the appropriate dose and dosing frequency.
- In people with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- Patients should not decrease or stop taking any of their other asthma, nasal polyps, or hive medicine unless their healthcare provider tell them to.
- Patients may not see improvement in their symptoms right away after XOLAIR treatment. If their asthma symptoms do not improve or get worse, call their healthcare provider.
- If a patient injects more XOLAIR than prescribed, call their healthcare provider right away.

What are the possible side effects of XOLAIR?

XOLAIR may cause serious side effects, including:

- Cancer. Cases of cancer were observed in some people who received XOLAIR.
- Inflammation of your blood vessels. Rarely, this can happen in people with asthma who receive XOLAIR. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by XOLAIR. A patient should tell their healthcare provider right away if they have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of their arms or legs.
- Fever, muscle aches, and rash. Some people get these symptoms 1 to 5 days after receiving a XOLAIR injection. If a patient has any of these symptoms, 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. A healthcare provider can test the patient's stool to check if they have a parasite infection.

- Heart and circulation problems. Some people who receive XOLAIR have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision. It is not known whether these are caused by XOLAIR.

The most common side effects of XOLAIR:

- In adults and children 12 years of age and older with asthma: joint pain especially in the arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of the ears.
- In children 6 to less than 12 years of age with asthma: swelling of the inside of the nose, throat, or sinuses, headache, fever, throat infection, ear infection, abdominal pain, stomach infection, and nose bleeds.
- In adults with nasal polyps: headache, injection site reactions, joint pain, upper abdominal pain, and dizziness.
- 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.

Patients may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. Patients may also 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.

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of 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 employs nearly 16,000 people in the United States. For more information, please visit https://www.novartis.us.

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References

1. Xolair® Full Prescribing Information. Genentech, Inc.; April 2021.
2. Data on file. Genentech, Inc.

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