NOVARTIS

Novartis announces FDA approval of Xolair® (omalizumab) for pediatric allergic asthma

Jul 07, 2016

- -- Extension of indication makes Xolair the first and only approved biologic for pediatric patients six years and older with uncontrolled moderate to severe persistent allergic asthma
- -- Asthma is one of the most common long-term diseases in children1, affecting about 6.3 million younger than 18 years old in the US2
- -- More than 200,000 allergic asthma patients have been treated with Xolair since its approval for patients 12 years and older in 20033

EAST HANOVER, N.J., July 7, 2016 /PRNewswire/ -- Novartis today announced that the US Food and Drug Administration (FDA) has approved an expanded age range for Xolair® (omalizumab) to include children six to 11 years of age with moderate to severe persistent asthma, having a positive skin test or in vitro reactivity to an airborne allergen (perennial aeroallergen) and symptoms that are inadequately controlled with inhaled corticosteroids[4]. The previous age range for the asthma indication of Xolair was 12 years and older. This approval comes three months ahead of the FDA action date.

"Allergic asthma can be challenging for children," said Fabrice Chouraqui, President of Novartis Pharmaceuticals Corporation. "For a long time, there has been an unmet need in this young patient population. We're excited to now offer this allergic asthma treatment option, which has been established in patients 12 years of age and older, to doctors and their young patients starting at age six."

Asthma is one of the most common long-term diseases in children[1], affecting about 6.3 million younger than 18 years old or one in 12 children in the US[2]. An estimated 24 million people in the US have asthma[2]. Of this patient population, approximately 60% have allergic asthma[5]. In children, at least 80% of asthma is allergic[6].

"Uncontrolled allergic asthma can significantly affect the lives of children," said Cary Sennett, MD, PhD, President and CEO of the Asthma and Allergy Foundation of America (AAFA). "This approval helps address an important unmet need for these young patients and their caregivers."

Xolair was first approved in 2003 to treat adults and children 12 years of age and older with moderate to severe persistent allergic asthma not controlled by inhaled steroids. Since its US approval for patients 12 years and older, more than 200,000 patients with allergic asthma have been treated with the medicine[3]. In 2014, the FDA also approved Xolair to treat adults and children 12 years of age and older with 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 indicated for the treatment of 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).

This new pediatric approval was supported by multi-center, randomized, double-blind, placebo-controlled Phase III studies that assessed the efficacy and safety of Xolair in children aged six to 11 years with moderate to severe persistent uncontrolled allergic asthma. The primary study was a 52-week trial, with the primary endpoint measured at 24 weeks[4]. Supportive safety and efficacy data came from a 28-week study[4]. Additional

safety data came from a five-year non-randomized observational post-marketing study to evaluate the long-term safety of Xolair in patients 12 years and older[7].

About Allergic Asthma

Asthma is a chronic condition with inflammation and narrowing of the airways, as well as tightening of the muscles around the airways.

The symptoms of asthma and allergic asthma are the same—it's the triggers that are different. What makes allergic asthma a unique type of asthma is the cause of its symptoms: exposure to year-round allergens in the air (such as pet dander and dust mites). If you have allergic asthma, allergens like these can bring on your allergic asthma symptoms and attacks.

- When an allergen enters your body, your immune system identifies it as something harmful
- Your immune system responds by releasing a substance called immunoglobulin E (or IgE)
- IgE plays a key role in the development of allergic asthma symptoms. It binds to allergens, which causes the release of chemicals that can lead to inflammation (swelling) in and around the lungs. This can trigger an allergic asthma attack

People with allergic asthma may have higher levels of IgE because of the way their immune system reacts to allergens. For some, blocking IgE has been shown to be a helpful part of their allergic asthma treatment plan. If you think you may have allergic asthma, ask your doctor about how much IgE is in your body.

About Xolair

Xolair for subcutaneous use is an injectable prescription medicine used to treat:

- moderate to severe persistent asthma in patients six years of age and older whose symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens.
- chronic idiopathic urticaria (CIU; chronic hives without a known cause) in patients 12 years of age and older 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, acute bronchospasm or status asthmaticus.

In the US, Genentech, Inc. and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

Important Safety Information

The most important information patients should know about XOLAIR is that 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 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. Talk with your healthcare provider about the best way to feed your baby while you receive XOLAIR.

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.
- In asthma patients, a blood test for a substance called IgE must be performed prior to starting XOLAIR to determine the appropriate dose and dosing frequency.
- In patients with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- Patients must not decrease or 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 regarding the risk of anaphylaxis.
- 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. Tell your healthcare provider right away if you have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of your arms or legs.
- 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.
- 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 this is caused by XOLAIR.

The most common side effects of XOLAIR:

- In adults and children 12 years of age and older with asthma: pain especially in the arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of the ears.
- In children 6 to less than 12 years of age with asthma: common cold symptoms, headache, fever, sore throat, pain or discomfort of your ear, abdominal pain, nausea, vomiting and nose bleeds.
- 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 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 at www.xolair.com for additional Important Safety Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "need," "available," "can," "may," or similar terms, or by express or implied discussions regarding potential 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 are based on the current beliefs and expectations of management 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 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 be commercially successful in the future. In particular, management's expectations regarding Xolair could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety, quality or manufacturing issues, 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

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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and

amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

1. US Centers for Disease Control and Prevention. What Is Asthma? http://www.cdc.gov/asthma/faqs.htm. Accessed June 30, 2016.
2. US Centers for Disease Control and Prevention. National Current Asthma Prevalence. http://www.cdc.gov/asthma/most_recent_data.htm. Accessed June 30, 2016.
3. Data on file. Genentech, Inc, South San Francisco, CA.
4. Xolair® Full Prescribing Information. Genentech. July 2016.
5. Arbes S, Gergen P, Vaughn B, et al. Asthma cases attributable to atopy: Results from the Third National Health and Nutrition Examination Survey. J Allergy Clin Immunol 2007;120:1139-45.
6. Prevention of Allergy and Allergic Asthma. World Health Organization. Management of Noncommunicable Diseases Department. Chronic Respiratory Diseases and Arthritis. Based on the WHO/WAO Meeting on the Prevention of Allergy and Allergic Asthma. Geneva, 8-9 January 2002.
7. Long A, Rahmaroui A, Rothman K, et al. Incidence of malignancy in patients with moderate-to-severe asthma treated with or without omalizumab. J Allergy Clin Immunol. 2014;134:560-7.

Novartis Media Relations

Eric Althoff	Martin DeBenedetto
Global Media Relations	US Communications
+41-61-324-7999 (direct)	862-778-7619 (office)
+41-79-593-4202 (mobile)	973-738-4104 (mobile)
eric.althoff@novartis.com	martin.debenedetto@novartis.com

e-mail: us.mediarelations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis.
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

SOURCE Novartis Pharmaceuticals Corporation

Source URL: *https://qa1.novartis.us/news/media-releases/novartis-announces-fda-approval-xolair-omalizumab-pediatric-allergic-asthma*

List of links present in page

1. https://qa1.novartis.us/news/media-releases/novartis-announces-fda-approval-xolair-omalizumab-pediatric-allergic-asthma
2. http://www.xolair.com/
3. http://www.fda.gov/medwatch
4. http://www.xolair.com/
5. http://www.novartis.com/
6. http://twitter.com/novartis
7. http://www.cdc.gov/asthma/faqs.htm
8. http://www.cdc.gov/asthma/most_recent_data.htm
9. mailto:eric.althoff@novartis.com
10. mailto:martin.debenedetto@novartis.com
11. mailto:us.mediarelations@novartis.com
12. http://www.thenewsmarket.com/Novartis
13. mailto:journalisthelp@thenewsmarket.com