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Novartis announces US FDA approval of Xolair® for chronic idiopathic urticaria (CIU)

- Xolair® (omalizumab) is the first and only licensed therapy in the US for the nearly 50% of patients with chronic idiopathic urticaria (CIU) who do not respond to approved doses of H1-antihistamines1

- CIU is known as CSU (chronic spontaneous urticaria) outside of the US and is an unpredictable and debilitating form of chronic itch, hives and angioedema2-4

- US FDA approval of Xolair in CIU closely follows approval in the European Union (EU) for the treatment of CSU

Basel, 21 March 2014 – Novartis today announced that the US Food and Drug Administration (FDA) has approved Xolair® (omalizumab) for the treatment of chronic idiopathic urticaria (CIU), an unpredictable and debilitating skin disease that is known as chronic spontaneous urticaria (CSU) outside of the US. In the US, Xolair is indicated for CIU in adults and adolescents (12 years of age and above) who remain symptomatic despite H1-antihistamine treatment5. Until now, H1-antihistamines have been the only approved therapy for CIU in the US.

CIU / CSU is a severe and distressing skin condition characterized by red, swollen, itchy and sometimes painful hives on the skin that spontaneously present and re-occur for more than six weeks2,3,6. Up to 40% of CIU / CSU patients also experience angioedema, a swelling in the deep layers of the skin1.

“This approval from the FDA is great news for patients in the US suffering from CIU, a skin disease known as CSU in other parts of the world,” said David Epstein, Division Head of Novartis Pharmaceuticals. “Up to 50% of patients do not respond to approved doses of H1-antihistamines, which up until now have been the only licensed treatment for CIU in the US.”

At any given time, the prevalence of chronic urticaria (CU) is up to 1% of the world’s population4, and up to two thirds of these patients have CIU / CSU5,7. In the US, it is estimated that approximately 1.5 million people suffer from CIU / CSU4,8. Women are twice as likely than men to have the condition and most people develop symptoms between the ages of 20 and 401,8.

The US FDA approval is primarily based on positive and consistent results from two landmark phase III studies, ASTERIA I and II, which involved CIU / CSU patients not responding to approved doses of H1-antihistamines6,9,10. Xolair 300 mg and 150 mg met all primary endpoints across these studies, which also showed Xolair significantly improved itch and hives, including rapid itch relief, and in many cases completely cleared symptoms6,8,10. Quality of life was also significantly improved for patients treated with Xolair 300 mg6,9,10. Negative effects of CIU / CSU on quality of life may include sleep deprivation and psychological comorbidities such as depression and anxiety4.
Results from three pivotal phase III studies for Xolair in CIU / CSU were announced in 2013. Highlights from these studies that were previously reported include:

- In all three phase III studies, a significant proportion of patients became either completely free of itch and hives (range 34-44%; p<0.001 to p<0.0001 at 300 mg) or had their symptoms suppressed to minimal levels (52-66%; p<0.0001 at 300mg)\(^6,9,10\).

- In the ASTERIA II study, 44% of patients receiving Xolair 300 mg were itch-and hive-free after 12 weeks of treatment (p<0.0001)\(^6\).

- In the ASTERIA I study, Xolair-treated patients experienced a rapid reduction in itch and hives as early as Week 1, with the therapeutic benefit sustained over 24 weeks of active treatment (p<0.0001)\(^9\).

- In the GLACIAL study, more than half of patients had failed multiple therapies including H1-antihistamines (at up to four times the approved dose) and H2-antihistamines and/or leukotriene receptor antagonists (LTRAs)\(^10\). Patient response in GLACIAL was similar to that seen in ASTERIA I and II, leading to elimination or suppression of symptoms to minimal levels within 2 weeks of the start of treatment, and sustained throughout the 24 week treatment period\(^6,9,10\).

In the pivotal phase III studies, the incidence and severity of adverse events (AEs) was similar between Xolair and placebo recipients\(^6,9,10\).

Xolair was recently approved by European Commission (EC) as add-on therapy for CSU in adult and adolescent patients 12 years and above with inadequate response to H1-antihistamines. Xolair has also been approved for the treatment of refractory CSU in eight other countries: Egypt, Turkey, Guatemala, El Salvador, Bangladesh, Pakistan, Ecuador and the Philippines. Regulatory reviews are currently ongoing in more than 20 countries, including Canada, Australia and Switzerland.

Xolair is being jointly developed by Novartis and Genentech, Inc.

**About Xolair\(^8\)**

Xolair is a targeted therapy that binds to immunoglobulin E (IgE). Xolair suppresses histamine-induced skin reactions, probably through its reduction of IgE and downstream effects on cellular activation mechanisms\(^11\). Research is ongoing to understand the mechanism of action of Xolair in CIU / CSU, which could lead to a deeper understanding of how the disease develops\(^1\).

In addition to the US approval of Xolair for CIU, Xolair is approved for the treatment of CSU in the European Union and in eight other countries. Xolair is approved for the treatment of moderate to severe persistent allergic asthma in more than 90 countries, including the US since 2003 and the EU since 2005 and has over 400,000 patient years of exposure. In the EU, it is also approved for the treatment of severe persistent allergic asthma in children (aged six and above), adolescents and adults. In addition, a liquid formulation of Xolair in pre-filled syringes has been approved in the EU and launched in most European countries. In the US, Xolair for subcutaneous use in appropriate allergic asthma patients is co-promoted by Novartis Pharmaceuticals Corporation and Genentech, Inc.

**About Novartis in Specialty Dermatology**

Novartis is committed to developing innovative, life-changing specialty dermatology therapies, redefining treatment paradigms and transforming patient care in severe skin diseases where there are remaining high unmet medical needs. The Novartis specialty dermatology portfolio includes Xolair\(^8\) (omalizumab) and secukinumab (AIN457). Xolair is a targeted therapy that is approved as an add-on therapy for the treatment of refractory chronic spontaneous urticaria (CSU) in the EU and in eight other countries, and for refractory chronic idiopathic urticaria (CIU) as it is known in the US. Regulatory reviews are currently ongoing in more than 20 countries. Secukinumab is the first IL-17A inhibitor...
to have completed phase III registration studies in moderate-to-severe plaque psoriasis. There are also more than 10 compounds in early stage development for a wide range of severe skin diseases in the Novartis specialty dermatology portfolio. For more information about the Novartis commitment to severe skin disease care, please visit: www.skintolivein.com.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as “unpredictable,” “may,” “currently,” “ongoing,” “could,” “committed,” “commitment,” or by express or implied discussions regarding potential and recently approved new indications or labeling for Xolair, potential marketing approvals for AIN457 or any other dermatology products, or regarding potential future revenues from such products. 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 AIN457 or any other dermatology products will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Xolair, AIN457 or any such other products 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 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.

References
9 Maurer M. Phase III randomized, double-blind, placebo-controlled study evaluating efficacy and safety of omalizumab in H1-antihistamine-refractory chronic idiopathic/spontaneous urticaria. European Academy of Dermatology and Venereology (EADV) annual meeting 2013. Oral Presentation. 5 October 2013, 11:30 a.m.

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