

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis reports new analysis showing Xolair[®] improving quality of life by 78% for chronic spontaneous urticaria patients**

- *New analysis from pivotal Phase III studies show Xolair[®] (omalizumab) significantly improved quality of life scores for Chronic Spontaneous Urticaria (CSU) patients compared to placebo^{1,2}*
- *Additional data at WCD show the consistent negative health impact and economic burden of CSU, including anxiety, depression, impact on work ability and health system costs^{3,4}*
- *CSU is a severe skin condition with symptoms such as persistent itching, swelling and a rash that spontaneously presents and re-occurs for more than six weeks⁵⁻⁷*

Basel, 12 June 2015 – Novartis announced today new analyses from pivotal Phase III registration studies showing Xolair[®] (omalizumab) helps patients with Chronic Spontaneous Urticaria (CSU) achieve significant improvements in quality of life measures. These findings were presented at the 23rd World Congress of Dermatology (WCD) in Vancouver, Canada.

CSU, which is known as Chronic Idiopathic Urticaria (CIU) in the US and Canada, is a severe and distressing skin condition with symptoms that include persistent itching, swelling and a rash (hives/wheals) that spontaneously appears on the skin and re-occurs for more than six weeks.⁵⁻⁷ In pivotal Phase III studies (ASTERIA I, ASTERIA II and GLACIAL), Xolair was found to be highly effective in either reducing or eliminating CSU symptoms, in patients for whom previous therapies had failed.⁸⁻¹⁰

In new post-hoc analyses presented at WCD, patients treated with Xolair for 12 weeks experienced significant improvements in quality of life by 78% (vs placebo 44%, $p < 0.0001$) as measured by the Dermatology Life Quality Index (DLQI) and up to 69% (vs placebo 40%, $p < 0.0001$) using the Chronic Urticaria Quality-of-Life Questionnaire (CU-Q₂oL).^{1,2}

“Chronic Spontaneous Urticaria is a poorly understood and debilitating skin condition that has a significant adverse impact on patients’ day-to-day activities and quality of life,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “These results confirm that Xolair, in addition to improving the symptoms of CSU, effectively improves the quality of life in patients affected by this unpredictable and painful disease.”

In addition, the ASSURE-CSU study found that, if left untreated, CSU, has a consistent negative impact on quality of life among patients. This was measured by the Urticaria Activity Score over 7 days (UAS7), CU-Q₂oL and DLQI.³ Similarly, the SOLVE-BOI study found that CSU patients compared to individuals without the disease have higher rates of complaints such as anxiety, depression, sleep difficulty, and lower physical and mental status.⁴ They are also 2-3 times more likely to visit a healthcare provider, require emergency medical care, or be hospitalized, and are twice as likely to take time off work (11.3% vs. 5.2%, $p < 0.0001$) or experience overall work impairment (36.9% vs. 20.2%, $p < 0.0001$).⁴

About the Pivotal Phase III Xolair CSU Studies

The pivotal Phase III ASTERIA I, ASTERIA II and GLACIAL studies evaluated the efficacy and safety of Xolair compared to placebo in nearly 1,000 CSU patients who remain symptomatic despite H1 antihistamines.⁸⁻¹⁰

Core efficacy results were announced in 2013. 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 300 mg).

A post-hoc analysis of improvement in health-related quality of life (HRQoL) among patients after 12 weeks of treatment with Xolair, as compared to placebo, measured the changes in the following validated Patient-Reported Outcomes Measures:

- The Dermatology Life Quality Index (DLQI), which gives a total score from 0-30, from best to worst QoL, whereby a score of >11 signifies that CSU/CIU has a very large to extremely large effect on a patient's life.
- The Chronic Urticaria Quality of Life questionnaire (CU-Q_{2oL}), which measures urticaria-specific QoL (total score from 0-100, from best to worst QoL).

After the 12-week treatment period, the following percentage improvements in HRQoL scores were observed across the three pivotal studies:

- Xolair: DLQI – 73-78%; CU-Q_{2oL} – 66-69%.
- Placebo: DLQI – 22-47%; CU-Q_{2oL} – 32-42%.

About the ASSURE-CSU study

ASSURE-CSU (**A**SSessment of the Economic and Humanistic Burden of Chronic **S**pontaneous/I^diopathic **U**rticaria Pati**E**nts) is the first international study to assess both the personal and economic burden of refractory CSU.

Data presented at WCD show that CSU had a similar and significant impact on HRQoL as measured by the DLQI and CUQoL in both the Canadian and U.K. cohorts.³ As expected, HRQoL impairment increased with disease severity.³ The findings support the need to measure quality of life scores among CSU patients to ensure a holistic and effective approach to disease management.³

About the SOLVE-BOI study

The SOLVE-BOI study analyzed data from the National Health and Wellness Survey (NHWS) conducted in five EU countries (France, Germany, Italy, Spain, and the United Kingdom) among respondents with chronic hives (a proxy for CSU) who indicated current use of a prescription for the condition (n=369;) compared to a control population of respondents who never experienced chronic hives (n=1476).⁴

The study found that patients with chronic hives experienced significant declines in HRQoL, more psychological complaints, higher rates of work impairment and healthcare utilization in the preceding 6 months, suggesting that CSU poses a substantial burden to patients and society.⁴

About Xolair®

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. Research is ongoing to understand the mechanism of action of Xolair in CSU, which could lead to a deeper understanding of how the disease develops.

Xolair is approved for the treatment of CSU in the European Union and in over 10 other countries, and for refractory chronic idiopathic urticaria (CIU) as it is known in the US and

Canada. 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.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "ongoing," "could," 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 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

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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 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 120,000 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>.

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