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Novartis showcases dermatology leadership on International Urticaria Day announcing new data to be presented at EADV 2014

- *New data for the IL-17A inhibitor AIN457 (secukinumab) in psoriasis and Xolair® in Chronic Spontaneous Urticaria (CSU) at EADV to highlight benefit to patients' quality of life*

- *Data continue to reinforce the landmark Phase III results of secukinumab in psoriasis and Xolair in CSU that showed consistent, fast efficacy and acceptable safety[1-4]*

- *Important head-to-head trial of secukinumab versus Stelara® (CLEAR), powered to evaluate superiority in clearing skin, completed patient enrolment in record time*

Basel, 1 October 2014 – Novartis announced today, on the first-ever International Urticaria Day, that 15 abstracts from the Novartis specialty dermatology portfolio, will be presented at the European Association of Dermatology and Venereology (EADV) Congress, 8-12 October, in Amsterdam, Netherlands.

The abstracts include new analyses of pivotal Phase III studies for AIN457 (secukinumab) in moderate-to-severe plaque psoriasis and Xolair® (omalizumab) in Chronic Spontaneous Urticaria (CSU) highlighting benefit to patients' quality of life. The new data to be presented at EADV continue to reinforce the previously presented landmark Phase III results of secukinumab in psoriasis and Xolair in CSU that showed consistent, fast efficacy in the treatment of these debilitating diseases[1-4].

In an update on ongoing Novartis dermatology trials, the Phase IIIb CLEAR study finished full enrolment of 679 moderate-to-severe plaque patients earlier than expected after recruitment started in February 2014. CLEAR is the second head-to-head secukinumab study versus a biologic treatment and will compare the long-term safety, tolerability and efficacy of secukinumab versus Stelara®* (ustekinumab), a current standard-of-care therapy. Results are anticipated in the coming months.

"Psoriasis and CSU are serious diseases that have a significant negative impact on quality of life," said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. "With our new data at EADV 2014 and the record-breaking enrolment timeline of the CLEAR study, we are excited to continue generating important clinical evidence of the impact of secukinumab and Xolair on patients."

Novartis specialty dermatology portfolio highlights at EADV 2014 include:

Oral presentations of Xolair's impact on CSU patients' quality of life from the Phase III studies

- Omalizumab reduced symptoms and improved health-related quality of life (HRQoL) in patients with CSU: an analysis from three randomized Phase III trials (abstract FC07; 11 October, 9.45 – 11.15 CET)
- A positive correlation between changes in urticaria symptoms (UAS7) and dermatologic-related quality of life (DLQI) and urticaria-specific quality of life

(CUQ2oL): Is it informative about the response to treatment in CSU patients? (abstract FC07; 11 October, 9.45-11.15 CET)

Highlights of electronic posters available throughout the EADV congress

- Psoriasis patients with clear or almost clear skin (categorized as Psoriasis Area and Severity Index 90 (PASI 90) to PASI 100) achieved greater health-related quality of life improvements than those with PASI 75 response, according to a sub-analysis of Phase III data
- Secukinumab shows efficacy regardless of baseline disease severity in moderate-to-severe plaque psoriasis patients, according to a pooled analysis of Phase III studies
- Secukinumab 300 mg demonstrated the highest probability of efficacy in clearing skin compared to other biologics currently approved to treat psoriasis, based on a mixed treatment comparison using data from a systematic literature review

Additional secukinumab Phase III analyses at EADV 2014 include data on sustained response, fast relief of disease burden, efficacy (at different treatment stages and in psoriatic arthritis patients), in addition to the further benefit of secukinumab treatment measured by health-related patient quality of life.

Additional analyses of Xolair pivotal Phase III studies include:

- First demonstration that improvements in urticaria symptoms result in substantial reductions in daytime sleepiness and sleep disturbance
- Pooled analyses of safety data from three pivotal Phase III studies (975 patients) with no new safety signals
- Demonstration that chronic hives, a symptom of CSU, is associated with significant burden across multiple areas of quality of life, greater impairment in work and increased utilization of health resources from the patients' perspective

Novartis-sponsored symposia

- A straight pathway for patients with chronic spontaneous urticaria (9 October, 17:00 – 18:30 CET)
- Revealing a clear path towards a new era in the management of psoriasis (10 October, 17:00 – 18:30 CET)

About AIN457 (secukinumab)

AIN457 (secukinumab) is a fully human monoclonal antibody (a special type of infection fighting cell produced in a laboratory) being investigated for diseases that affect the immune system[5-7]. Secukinumab stops a protein called interleukin-17A (IL-17A) from its involvement in the development of psoriasis and other inflammatory diseases, including psoriatic arthritis (PsA) and ankylosing spondylitis (AS)[5-9]. IL-17A is found in high concentrations in skin affected by psoriasis and is a preferred target for investigational therapies[5-10].

Secukinumab is the first medicine selectively targeting IL-17A with positive Phase III results for the treatment of psoriasis and PsA. Phase III results for secukinumab in moderate-to-severe plaque psoriasis were first presented in October 2013 and March 2014. Following the presentation of the first psoriasis Phase III results in secukinumab in October 2013, EU and US regulatory filings were submitted at the end of 2013. Results from Phase III studies for arthritic conditions (PsA and AS) will be presented in late 2014.

About Xolair®

Xolair (omalizumab) is a targeted therapy that binds to immunoglobulin E (IgE)[11,12]. 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 CSU, which could lead to a deeper understanding of how the disease develops[12].

Xolair is approved for the treatment of refractory chronic spontaneous urticaria (CSU) in the EU and Switzerland, as well as in more than 25 other countries, and in the US and Canada for refractory chronic idiopathic urticaria (CIU) as it is known there. 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 500,000 patient years of exposure[11]. 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 Australia and in the EU and launched in most European countries. Novartis co-promotes Xolair with Genentech/Roche in the US and shares a portion of the operating income, but does not book US sales.

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® (omalizumab) and secukinumab (AIN457). 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 words such as “launch,” “aims,” “forthcoming,” “will,” “ongoing,” “anticipated,” “commitment,” “continuing,” “launched,” “investigational,” “could,” “committed,” “early stage development,” or by express or implied discussions regarding potential marketing approvals for AIN457 or any other dermatology products, potential and recently approved new indications or labeling for Xolair, or regarding potential future revenues from such products. 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 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 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, Xolair 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; global trends toward health care cost containment, including ongoing pricing pressures; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; unexpected manufacturing issues; general economic and industry conditions, 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, 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 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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*Stelara® is a registered trademark of Janssen Biotech, Inc.

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