Novartis real world study shows almost half of chronic urticaria patients are not receiving any treatment despite significant disease burden

- **Urgent need to improve management of chronic urticaria (CU) — a disease that causes itchy, persistent hives and swelling which last more than 6 weeks or recur over months or years — highlighted by study of over 3,700 patients**

- **42% of CU patients studied are not receiving any treatment for their debilitating condition and 83% show a negative impact on their quality of life**

- **This further confirms that many chronic spontaneous urticaria (CSU) patients are not treated according to recommended guidelines** — Xolair® (omalizumab)* is the only licensed third-line treatment for CSU, a type of CU

**Basel, June 20, 2017** — Novartis announced today new baseline results from a real world study of 3,733 chronic urticaria (CU) patients showing many are not receiving adequate care, with almost half (42%) not receiving any treatment at all for the debilitating disease despite 83% suffering a negative impact on their quality of life. The findings are consistent with earlier research that found many chronic spontaneous urticaria (CSU) patients are not treated according to recommended guidelines that include Xolair® (omalizumab) — the only licensed option for CSU, a type of CU. The findings were presented at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress in Helsinki, Finland.

The results are part of the worldwide non-interventional AWARE study. These data from 12 European countries reveal the significant impact of CU — a severe disease that causes itchy, persistent hives and painful swelling for at least 6 weeks and in a substantial number of cases even years or decades. Symptoms may occur in visible and highly-sensitive areas of the body, such as around the eyelids, lips, and mouth, and the psychological and social impact of the disease is significant.

“Chronic urticaria is a serious disease that greatly impacts the quality of life, yet seems to be severely undertreated,” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “These findings reinforce the urgent need to improve the management of chronic urticaria in line with treatment guidelines, calling for a treatment goal of a ‘symptom free patient’.”

More than half of the patients reported the effect of CU on their QOL as moderate, very large, or extremely large. This substantial QOL impact was observed in 51% in Southern European countries (Belgium, France, Portugal, Spain, Italy, and Greece), 54% of patients in Nordic countries (Sweden, Norway, and Denmark), 56% of German patients, 61% of UK patients, and as many as 85% of Russian patients.

Importantly, many patients receiving treatment still reported a substantial QOL impact, indicating inadequate symptom relief even in those currently on therapy. Nordic patients were most likely to be receiving any treatment (74%), followed by patients in Germany (61%), South European countries (58%), the UK (52%), and Russia (39%).
About CU
CU is a severe disease that is characterized by the reoccurrence of persistent hives and/or sometimes painful swelling for six weeks or more.

At any given time, the prevalence of CU is up to 1% of the world’s population, and up to two thirds of these patients have CSU – a form of the condition that can occur unpredictably without an identifiable trigger. In 30 to 50% of cases, CU lasts for up to a year, however in a substantial amount of patients CU can last anything from 1 to 5 years and in some it can last for decades.

Although CU has a significant impact on patients’ quality of life, research has highlighted that some physicians disregard the disease as a trivial condition.

About AWARE
AWARE (A World-wide Antihistamine-Refractory Chronic Urticaria Patient Evaluation) is an ongoing prospective observational study designed to assess CU in the real-life setting. These baseline interim results are from 12 European countries included in the study. Data was collected from patients aged 18 years or older and refractory to at least one course of H1-AH, and included pharmacological treatments and QOL measured by the Dermatology Life Quality Index (DLQI).

*Xolair® is the only licensed third line treatment and is indicated as add-on therapy for the treatment of CSU, a type of CU, in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment. The study also included ciclosporin and montelukast which are recommended third-line treatments which are used off-label to treat CU.

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The foregoing release contains forward-looking statements that can be identified by words such as “recommended,” “seems to be,” “calling for,” “ongoing,” 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 clinical trial results and additional analysis of existing clinical data; 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 and reimbursement pressures; 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
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References
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