IR & MEDIA UPDATE

Novartis ligelizumab (QGE031) receives FDA Breakthrough Therapy designation for patients with chronic spontaneous urticaria (CSU)

- Ligelizumab is the first treatment to receive FDA Breakthrough Therapy designation in chronic spontaneous urticaria (CSU) in patients with an inadequate response to H1-antihistamines¹

- Currently there are limited approved therapies for patients with CSU, also known as chronic idiopathic urticaria (CIU)

- Breakthrough Therapy designation suggests ligelizumab has the potential to provide a substantial benefit over existing available treatments

- U.S. regulatory filing in CSU is anticipated in 2022

Basel, January 14, 2021 — Novartis today announced that the U.S. Food and Drug Administration (FDA) has granted ligelizumab (QGE031) Breakthrough Therapy designation for the treatment of chronic spontaneous urticaria (CSU), also known as chronic idiopathic urticaria (CIU), in patients who have an inadequate response to H1-antihistamine treatment.

CSU is an unpredictable and severe disease of the skin, affecting 0.5-1% of the global population at any time². It is characterized by the development of itchy, painful wheals (hives), swelling (angioedema), or both, lasting for at least 6 weeks and occurring with no known cause³. CSU can be challenging or frustrating for patients due to the severity and unpredictable nature⁴. It most commonly persists for 1-5 years, but in some cases even longer³.

“Chronic spontaneous urticaria is a debilitating disease that may significantly impact a patient’s life. With so few treatment options available, patients are looking for more and better therapies to control their disease,” said Angelika Jahreis MD, PhD, Novartis Global Head Development Unit Immunology, Hepatology & Dermatology. “The FDA Breakthrough Therapy designation recognizes the need for a more effective treatment for this unpredictable, systemic and debilitating disease.”

According to FDA guidelines, treatments that receive Breakthrough Therapy Designation must target a serious or life-threatening disease and demonstrate a potential substantial improvement over existing therapies on one or more significant clinical endpoints⁵.
About ligelizumab
Ligelizumab (QGE031) is a next generation monoclonal anti-immunoglobulin E (IgE) antibody. Ligelizumab is thought to work by blocking the IgE/FcεRI pathway, a key driver of the inflammatory process in CSU. In a Phase IIb dose-finding trial, more patients experienced complete resolution of wheals (hives) with ligelizumab compared with Xolair® (omalizumab). No safety concerns were found with ligelizumab compared with omalizumab or placebo in a Phase IIb dose-finding trial in CSU patients with inadequate control on antihistamines. Ligelizumab compared with omalizumab is currently being investigated in ongoing Phase III clinical trial programs including PEARL 1 and PEARL 2 (NCT03580369 and NCT03580356). The clinical trials have recruited more than 2,000 patients globally across 48 countries and results are expected in the second half of 2021.

About Novartis in CSU
Novartis is curious about the science beneath the skin and dedicated to reimagining the care of patients with diseases that can severely limit quality of life such as CSU, psoriasis, acne and atopic dermatitis. Advancing ligelizumab further strengthens the immuno-dermatology pipeline of Novartis. In the US, Novartis and Genentech, a member of the Roche Group, work together to develop and co-promote Xolair. Outside the US, Novartis markets Xolair and records all sales and related costs. Xolair is indicated as an add-on therapy for the treatment of CSU. Novartis is also testing remibrutinib (LOU064), a Bruton’s tyrosine kinase (BTK) inhibitor that is being tested in Phase II clinical studies for CSU.

Disclaimer
This media update contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this media update, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 the investigational or approved products described in this media update will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products 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; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.
About Novartis
Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at https://twitter.com/novartisnews
For Novartis multimedia content, please visit https://www.novartis.com/news/media-library
For questions about the site or required registration, please contact media.relations@novartis.com

References

Novartis Media Relations
E-mail: media.relations@novartis.com

Antonio Ligi
Novartis Global External Communications
+41 61 324 1374 (direct)
antonio.ligi@novartis.com

Louise Clark
Novartis Pharma Communications
+41 61 324 2970 (direct)
louise.clark@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@novartis.com

# # #
Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

<table>
<thead>
<tr>
<th>Central</th>
<th>North America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samir Shah</td>
<td>Sloan Simpson</td>
</tr>
<tr>
<td>+41 61 324 7944</td>
<td>+1 862 778 5052</td>
</tr>
<tr>
<td>Thomas Hungerbuehler</td>
<td></td>
</tr>
<tr>
<td>+41 61 324 8425</td>
<td></td>
</tr>
<tr>
<td>Isabella Zinck</td>
<td></td>
</tr>
<tr>
<td>+41 61 324 7188</td>
<td></td>
</tr>
</tbody>
</table>