Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
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MEDIA UPDATE

Novartis data show achieving complete control of chronic spontaneous urticaria (CSU) improves overall quality of life, as reported by patients

- *Data analysis shows that preventing the symptoms of CSU (achieving complete control) improves overall health-related quality of life (HRQoL); including sleep and work productivity, among other measures*[1]

- *Complete control of CSU symptoms, assessed by a composite of patient reported outcomes (PROs), is more likely to be achieved and sustained with ligelizumab than Xolair® (omalizumab) or placebo*[2]

- *Phase III results are expected in H2 2021 with first regulatory filing in 2022*

Basel, September 29, 2021 — Novartis, a leader in immuno-dermatology and rheumatology, today announced new analysis from a Phase IIb study demonstrating the importance of achieving complete control of chronic spontaneous urticaria (CSU) symptoms in improving overall health-related quality of life (HRQoL) for patients[1]. Complete control of symptoms brings enormous benefit to people with CSU and is associated with improvements in key HRQoL measures such as overall quality of life, sleep interference, activity interference and work impairment[1,3]. There is a marked decline in these improvements to quality of life even when patients are living with only a low level of CSU symptoms[1].

Complete control of CSU symptoms was assessed by a composite of patient reported outcomes (PROs) and was shown to be more likely achieved and sustained with ligelizumab than Xolair® (omalizumab) or placebo[2]. These data were presented at the European Academy of Dermatology and Venereology (EADV) 30th Anniversary Congress.

CSU is a severe and unpredictable disease of the skin, affecting up to 1% of the global population at any time[4]. When compared with the general population, patients with CSU are twice as likely to experience difficulty sleeping, anxiety, distress and depression[5-7]. Many people with CSU do not achieve complete control of signs and symptoms despite using standard-of-care treatments (antihistamines and omalizumab)[1,4,8].

The data show that ligelizumab was more likely to provide complete control of CSU symptoms than omalizumab when assessed using a composite of PROs[2]. A patient free from signs and symptoms of urticaria with concurrent hive severity score (HSS7)=0, itch severity score (ISS7)=0 and angioedema activity score (AAS7)=0 was considered to have CSU completely controlled. Concurrent Dermatology Life Quality Index (DLQI)=0-1 indicated a patient being CSU free[2]:

- At Week 12, the proportion of patients showing CSU completely controlled was 44.1% with ligelizumab 72 mg (*P*=0.007 vs omalizumab, and *P*=0.003 vs placebo), 40.0% with ligelizumab 240 mg (*P*=0.025 vs omalizumab, and *P*=0.004 vs placebo), 23.5% with omalizumab (*P*=0.021 vs placebo) and 0.0% with placebo. The proportion of CSU-free patients was 38.1% with ligelizumab 72 mg (*P*=0.008 vs omalizumab, and *P*=0.006 vs placebo), 35.3% with ligelizumab 240 mg (*P*=0.020 vs omalizumab, and *P*=0.007 vs placebo), 18.8% with omalizumab (*P*=0.035 vs placebo) and 0.0% with placebo.
- At Week 20, the proportion of patients with CSU completely controlled was 33.3%, 34.1%, 25.9% and 4.7%, and for CSU-free patients was 32.1%, 31.8%, 23.5% and 4.7% for ligelizumab 72 mg, 240 mg, omalizumab and placebo, respectively.
- During the treatment-free follow-up period, at Week 28, the proportion of patients remaining CSU free for ligelizumab 72 mg, 240 mg, omalizumab and placebo was 22.8%, 25.0%, 5.3% and 4.9%, respectively.

"Novartis is committed to the discovery and development of medicines that can ease the burden of immuno-dermatological diseases, which impact more than 100 million people worldwide," said Angelika Jahreis M.D., Ph.D., Novartis Global Head Development Unit Immunology, Hepatology & Dermatology. "These Phase II results are encouraging as they speak to the benefits of symptom control as reported directly by patients. This is particularly revealing as we know that established methods of assessing disease impact such as the Urticaria Activity Score of 7 days (UAS7) can sometimes fail to capture a patient's entire experience of living with CSU."

Novartis will also present late-breaking Phase II data for remibrutinib in CSU, showing that multiple doses provide significant improvements from baseline versus placebo with a favorable safety profile across the entire dose range. Remibrutinib is being investigated as a potential oral treatment across a number of immune-mediated conditions.

Lay summaries for the Phase IIb ligelizumab data and other key abstracts presented at EADV 2021 are available from the Novartis website: ***https://www.novartis.com/our-focus/immunology-dermatology/abstract-summaries-eadv.***

Novartis in chronic spontaneous urticaria (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. Novartis is committed to developing medicines that will advance the treatment of CSU, so patients are able to live their lives without the distressing and unpredictable symptoms of this debilitating disease. These include ligelizumab (QGE031) a next generation high-affinity monoclonal anti-immunoglobulin (Ig) E antibody and remibrutinib (LOU064) a potentially best-in-class oral BTK inhibitor. It is intended that these investigational therapies will complement Xolair, our existing approved add-on therapy for CSU.

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.

About ligelizumab
Ligelizumab (QGE031) is a next generation high-affinity monoclonal anti-immunoglobulin (Ig) E antibody. Ligelizumab is thought to work by blocking the IgE/FcεRI pathway, a key driver of the inflammatory process in CSU[9,10]. In a Phase IIb dose-finding trial, more patients experienced complete resolution of wheals (hives) with ligelizumab compared with Xolair® (omalizumab)[11]. 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[11]. Ligelizumab compared with omalizumab is currently being investigated in ongoing Phase III clinical trials 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[12,13].

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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 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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

Michael Meo
Novartis US External Communications
+1 862 274 5414 (direct)
michael.meo@novartis.com

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

Julie Masow
Novartis US External Communications
+1 862 579 8456
julie.masow@novartis.com

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

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Thomas Hungerbuehler	+41 61 324 8425	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973 876 4912