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Novartis ligelizumab (QGE031) more effective than Xolair® at inhibiting immunoglobulin E pathway responsible for chronic spontaneous urticaria

- *Data show ligelizumab binds to immunoglobulin E (IgE), a key driver of chronic spontaneous urticaria (CSU), with significantly higher affinity than current standard of care Xolair (omalizumab)¹*
- *The study published in Nature Communications suggests ligelizumab has the potential to be more effective than Xolair in treating CSU*
- *Earlier Phase IIb study results show more patients are completely symptom-free from CSU with ligelizumab than Xolair²*
- *CSU is a distressing and unpredictable skin condition with many patients having uncontrolled symptoms³*

Basel, January 09, 2020 – Novartis, a leader in immuno-dermatology, announced mechanistic study results showing ligelizumab is more effective at inhibiting the major pathogenic IgE/FcεRI pathway in chronic spontaneous urticaria (CSU), than current therapy Xolair® (omalizumab)¹. Ligelizumab can bind to IgE with an 88-fold higher affinity than Xolair¹. The data show ligelizumab and Xolair recognize and bind differently to IgE, with ligelizumab resulting in a significantly enhanced blockade of IgE/FcεRI signaling.

“This mechanistic research study is a great step forward in understanding how different anti-IgE treatments can have qualitatively and functionally distinct inhibition profiles”, said one of the investigators of the study, PD Dr. Alexander Eggel, University of Bern, Switzerland.

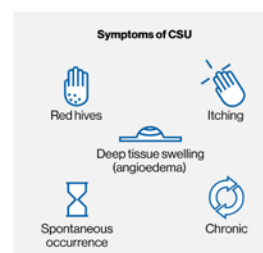
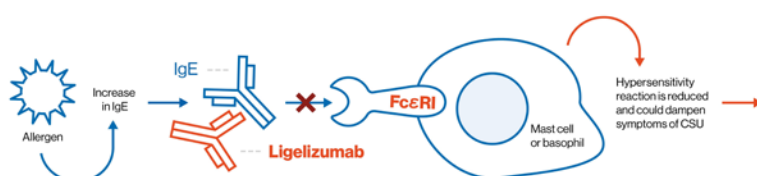
“We were recently encouraged by previous clinical study results showing more patients are completely symptom-free from CSU with ligelizumab than Xolair²,” said Eric Hughes, Global Development Unit Head for Immunology, Hepatology and Dermatology, Novartis. “This mechanistic study further supports those findings as we look to reimagine care to bring better treatment options for patients with CSU.”

Mechanism of action of ligelizumab in chronic spontaneous urticaria (CSU)

FcεRI is a receptor found on effector cells, such as mast cells and basophils and has a high affinity for IgE (immunoglobulin E)

IgE plays a central role in acute allergic reactions and chronic inflammatory allergic diseases

Ligelizumab is a monoclonal antibody that binds to IgE and consequently blocks the FcεRI pathway¹



¹ Gasser P et al. The mechanistic and functional profile of the therapeutic anti-IgE antibody ligelizumab is different from omalizumab. Nat Commun 2020; 11:85

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About Novartis in CSU

Advancing ligelizumab further strengthens the immuno-dermatology pipeline of Novartis. In the US, Novartis and Genentech, Inc. work together to develop and co-promote Xolair. Outside the US, Novartis markets Xolair and records all sales and related costs. Xolair,

indicated as an add-on therapy for the treatment of CSU, is the only therapy recommended by the global guideline on chronic urticaria (CU) for patients unresponsive to antihistamines. Ligelizumab (QGE031) is currently being investigated in an ongoing Phase III clinical trial program that includes Phase III trials PEARL 1 and PEARL 2 that are globally recruiting more than 2,000 patients across 48 countries around the world.

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 more than 750 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 www.novartis.com.

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1. Gasser P, et al. The mechanistic and functional profile of the therapeutic anti-IgE antibody ligelizumab is different from omalizumab. *Nat Commun* 2020; 11:165.
2. Maurer M, et al. Ligelizumab for chronic spontaneous urticaria. *N Engl J Med* 2019;381:1321–1332.
3. Maurer M, et al. Unmet clinical needs in chronic spontaneous urticaria: A GA(2)LEN task force report. *Allergy* 2011; 66:317–330.

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