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# Novartis data show more patients are completely symptom-free from chronic spontaneous urticaria with ligelizumab (QGE031) than Xolair® 300 mg

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- Results from a Phase IIb dose-finding study show an average complete response rate of 42% for doses 240 mg and 72 mg ligelizumab at Week 12 compared with 26% for those taking 300 mg Xolair's dose (omalizumab)[1]
- Complete control of hives achieved by 51% and 42% of patients treated with ligelizumab (72 mg and 240 mg respectively) at Week 12 compared with 26% of patients treated with Xolair[1] 300 mg
- Ligelizumab (QGE031), a monoclonal antibody, blocking the IgE/FceR1 pathway, is being developed as a treatment option for chronic spontaneous urticaria (CSU) patients whose symptoms are inadequately controlled by H1-antihistamines[2]
- Ligelizumab (QGE031) is currently being investigated in an ongoing Phase III clinical trial program which includes Phase III trials PEARL 1 and PEARL 2 that are globally recruiting more than 2,000 patients across 48 countries around the world[3][4]
- Data from the Phase IIb dose-finding study were published in The New England Journal of Medicine[1]

Basel, October 8, 2019 - "These study results are encouraging as we look to support patients with effective treatments to manage the debilitating symptoms of CSU," said Marcus Maurer, MD, professor of dermatology and allergy and director of research at the Department of Dermatology and Allergy, Allergie-Centrum-Charité of the Charité–Universitätsmedizin in Berlin, Germany. "CSU is a severe skin disease that significantly impacts the lives of patients, who may experience unpredictable and persistent itchy hives, sometimes with painful swelling of the skin."

"Around half of patients on current standard-of-care treatment, including omalizumab, for CSU continue to have uncontrolled symptoms[5]," said Eric Hughes, Global Development Unit head for Immunology, Hepatology and Dermatology. "We're encouraged by the results of this study, which is a step forward in our journey to reimagine care in immuno-dermatology to bring better treatment options for patients."

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# References

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[3] ClinicalTrials.gov. A Phase III Study of Efficacy and Safety of Ligelizumab in the Treatment of CSU in Adolescents and Adults Inadequately Controlled With H1-antihistamines. Available online at: <a href="https://clinicaltrials.gov/ct2/show/NCT03580369">https://clinicaltrials.gov/ct2/show/NCT03580369</a>. Last accessed October 2018

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