INTRODUCTION

• Ligelizumab, a next generation high-affinity humanised monoclonal anti-IgE antibody, has been shown to be effective in patients with chronic spontaneous urticaria (CSU) inadequately controlled by H1-antihistamines during a Phase 2b core study (NCT02477332).

• A numerically higher percentage of patients had complete control of CSU symptoms with ligelizumab therapy of 72 mg or 240 mg, than with 300 mg omalizumab or placebo.

• Here, in the Phase 2b extension study (NCT02649218), we assess the response to ligelizumab 240 mg in patients who did not achieve complete urticaria activity control with omalizumab in the core study.

METHODS

Study Design and Patients

• In the 20-week Phase 2b core study, adult patients with moderate to severe CSU (defined by a 7-day Urticaria Activity Score [UAS7]=16) were randomised to receive ligelizumab 24, 72 or 240 mg, omalizumab 300 mg, ligelizumab 120 mg (single dose) or placebo every 4 weeks (q4w) for five injections.

• Following a 16-week washout period after last dose in the core study, eligible patients (UAS7≥12) entered a 52-week open-label, single-arm (ligelizumab 240 mg q4w) Phase 2b extension study (Figure 1).

RESULTS

• From the core study population, 70.6% (226/320) of patients entered the extension study after the washout period (Week 32). In total, 88.9% of these patients (212/242) completed the extension study. A total of 53 patients were treated with omalizumab in the core study and were re-treated with ligelizumab in the extension study. Among these, 37 patients did not achieve complete control of urticaria (UAS7=0) at Week 12 of the core study (Figure 2).

• Here, in the Phase 2b extension study (NCT02649218), we assess the response to ligelizumab 240 mg in patients who did not achieve complete urticaria activity control with omalizumab in the core study.

• Overall, a numerically larger proportion of CSU patients treated with ligelizumab showed complete symptom control after 20 weeks vs. omalizumab.

• CSU patients who had previously not reached a complete response after 12 weeks of treatment with omalizumab, achieved numerically greater reductions in UAS7 when re-treated with ligelizumab vs. omalizumab.

• Ligelizumab can be effective and may provide added benefit of achieving complete control of urticaria in patients with CSU.

CONCLUSIONS

• Overall, a numerically larger proportion of CSU patients treated with ligelizumab showed complete symptom control after 20 weeks vs. omalizumab.

• CSU patients who had previously not reached a complete response after 12 weeks of treatment with omalizumab, achieved numerically greater reductions in UAS7 when re-treated with ligelizumab vs. omalizumab.

• Ligelizumab can be effective and may provide added benefit of achieving complete control of urticaria in patients with CSU.

ACKNOWLEDGEMENTS

All authors participated in the development of the poster for presentation. The authors thank Hayley Furting, PhD (Novartis Ireland Ltd.) and Mohammad Hanon PhD (Novartis Hyderabad Ltd.) for editorial and medical writing support, which was funded by Novartis Pharma AG, Switzerland in accordance with the Good Publication Practice (GPP3) guidelines (http://www.bmpgp.org/gpp3). This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland.

DISCLOSURES

M Meta reports personal fees from Araekz, moxat, Novartis, Roche, Sanofi and from Ulsan. M Hide has received lecture and consultation fees from TAHO Pharmaceutical, Novartis, MSD, Tokushu Seiyaku, Mitsubishi Tanabe Pharma Ulsan and Kyowa Hakko Kirin. G Sussman has received research support from Amgen, AstraZeneca, DBV Technologies, Genentech, Kedron S.p.A, Leo Pharma Inc., Novartis, Nuovo Pharmaceuticals Inc., Sanofi, SanoFidevice, Merck and Schering-Plough, is a medical advisor and/or has received payment for lectures from Merck, Novartis, CSL Behring, Pfizer, Anaphylaxis Canada, the Allergy and Immunology Society of Ontario and the Canadian Hereditary Angioedema Network. K Sitz has provided consultancy to Biocytex Pharmaceuticals Inc. M Maurer is or recently was a speaker and/or advisor for and/or has received research funding from Aimmune, Alkara, Araekz, AstraZeneca, Cubist, FAES, Genentech, GlaxoSmithKline, Kyowa Kirin, Leo Pharma, Menarini, Novartis, Moxat, MSD, Roche, Sanofi, Third Harmonic, UCSF, and Ulsan. T Savannah and R Janocha are full-time employees of Novartis Pharma AG, Basel Switzerland. E Hua is an employee of Shanghai Novartis Trading Ltd., Shanghai, China.

Poster presented at: 29th European Academy of Dermatology and Venereology Congress, 29 – 31 October, 2020 (virtual)