INTRODUCTION

- Ligilizumab is a next generation, high affinity humanised monoclonal anti-IgE antibody, which has control of symptoms in a higher percentage of patients compared with omalizumab in a phase 2b trial (NCT02477332).
- CSU disease activity and quality of life (QoL) impairment can be assessed by the use of the Urticaria Activity Score (UAS) / Angioedema Activity Score (AAS) and of the Dermatology Life Quality Index (DLQI), respectively.
- Here, we analysed changes of the weekly UAS (UAS7), CSU disease activity and quality of life (QoL) impairment with omalizumab in a phase 2b trial (NCT02477332)1.

RESULTS

- Patient disposition during the core Phase 2b trial is shown in Figure 2 – Data were available from 165 patients with CSU and angioedema at baseline.
- The mean (standard deviation) UAS7 baseline scores for patients treated with ligilizumab 72 mg, 240 mg, omalizumab and placebo were: 33.1 (6.66), 29.8 (7.46), 30.2 (8.51) and 32.0 (6.49), respectively (Figure 3A).
- Improvements in symptoms (reduction in UAS7 score) in each treatment arm were accompanied by improvement in DLQI (Figure 3A and 3C).

METHODS

- Adult patients with CSU inadequately controlled by an H1-antihistamine and with moderate to severe disease activity (UAS7≥16) were randomised to receive subcutaneous ligilizumab 72 or 240 mg, omalizumab 300 mg, or placebo every 4 weeks ( qw4) for 20 weeks (Figure 1).
- Changes from baseline (CBF) to Week 4, 12 and 20 in UAS7, AAS7 and DLQI in each arm (ligilizumab 72 mg, 240 mg, omalizumab 300 mg and placebo) were analyzed.
- Additionally, Pearson correlation coefficients (R-Value) of UAS7 / AAS7 with DLQI on pooled data over time (baseline to Week 20) were calculated.

CONCLUSIONS

- This exploratory analysis shows that CSU patients with angioedema treated with ligilizumab 72 and 240 mg show a similar improvement trend on UAS7, AAS7 and DLQI in comparison to omalizumab and placebo over time.
- DLQI improvements correlate well with the UAS7 and AAS7 scores improvement, which reflects the reduction of disease symptoms.
- Results of this Phase 2b trial support the two ongoing Phase 3 trials examining the efficacy and safety of ligilizumab 72 and 120 mg qw4 treatment up to 1 year in patients with CSU inadequately controlled with H1-antihistamines at approved doses.

Reference


Disclosures

González-Arévalo A has served as medical advisor for UCB Pharma, Genentech, Novartis, Pfizer, GSK, Sanofi, and received research grants supported by UCB Novartis, Novartis, Gifts from Inifusus Centro B – FEDER and has been involved in educational activities for UCB Pharma, Novartis, Genentech, Merck, Leo Pharma, GSK, AbbVie, Aclaris and Sanofi. Maurer H. has received research support and/or honoraria for consulting or lectures from Akebia, Alkazor, Pfizer, Merck, Merckle Recordati, Albat, Novartis, Roche, MSD, UCB, UCB, Sunovion. Soong W. has an editorial and/or clinical investigator and/or received speaker's honorarium and/or received consulting fee and/or grants and/or participated as a clinical investigator at the following companies: AbbVie, Alkazor Therapeutics, AstaZeneca, Care, Celgene, Genentech, GlaxoSmithKline, GlaxoSmithKline, Gwy, Optimmune, GlaxoSmithKline, Boehr, Vanda, Reclame, Asfod, Medo, Novartis, Pfizer, Ragenau, Sanofi and Veks. Bernstein J. A. has reported grants and personal fees from Novartis, AstaZeneca, Almirall and Genentech outside the submitted work. Severin T., Janocha R. and Balp M-M. is an employee of Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, United States. is an employee of Novartis, AstraZeneca, Almirall, and Genentech outside the submitted work. Samsung K. has received research support from Amgen, AstaZeneca, SBH, DBV technologies, Genentech, Kedrion S.p.A, Leo Pharma Inc., Novartis, Nuiv Pharmaceuticals Inc., Sanofi, Stallergenes, Merck and Schering-Poough. Rush is a medical advisor and/or has received payment for lectures from Merck, Novartis, CSB, Behring, Pfizer, Aparthys, Canada, the allergy Asthma and Immunology Society of Ontario and the Canadian Revascularizing Angiography Network. Mas M. reports personal fees from Akebia, mobico, Novartis, Roche, Sanofi and from UCB. Hidé M. has received lecture and/or consultation fees from RIAKO Pharmaceutical, Novartis, MSD, Teikoku Seiyaku, Mitsubishi Tanabe Pharma Usch and KyowaKirin- Kim. Shin K. has provided consultancy to BioCryst Pharmaceuticals Inc. Hu E. is an employee of Shanghai Novartis Trading Ltd., Shanghai, China. Gupta R. is an employee of Novartis Healthcare Pvt. Ltd., Hyderabad, India. Baer S. is an employee of Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, United States. The authors thank Nivedita Jangale and T. Achenbach, for editorial and medical writing support, which was funded by Novartis Pharma AG, Switzerland in accordance with Good Publication Practice (GPP3) guidelines (http://www.wipo.int/edp/en/gpp3).

Acknowledgements

All authors participated in the development of the poster for presentation. The authors thank Nivedita Jangale and Mohammad Farhad Haddad (Novartis Healthcare Pvt. Ltd., Hyderabad) for editorial and medical writing support, which was funded by Novartis Pharma AG, Switzerland in accordance with Good Publication Practice (GPP3) guidelines (http://www.wipo.int/edp/en/gpp3).