The Study Design of a Trial of Dupilumab in Adult Patients With Bullous Pemphigoid (BP): LIBERTY-BP ADEPT

Dedee F. Murrell[1], Pascal Joly[2], Victoria P. Werth[3,4], Elizabeth Laws[5], Leda P. Mannent[6], Bethany Beazley[7], Ariane Dubost-Brama[6], Arsalan Shabbir[7]

[1]University of New South Wales, Sydney, NSW, Australia; [2]Rouen University Hospital and INSERM 1234, Normandy University, Rouen, France; [3]Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA; [4]Corporal Michael J. Crescenz Veterans Affairs Medical Center, Philadelphia, PA, USA; [5]Sanofi, Bridgewater, NJ, USA; [6]Sanofi, Chilly-Mazarin, France; [7]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

Background

BP is a rare autoimmune skin-blistering disorder with a profound negative impact on quality of life, associated with burdensome morbidity and possible mortality. There is a need for effective targeted therapies with a demonstrated safety profile for BP. Dupilumab is a fully human monoclonal antibody that blocks the shared receptor component for interleukin (IL)-4 and IL-13, key and central drivers of type 2 inflammation that may play a role in BP. Published case series describe the use of dupilumab in patients with BP, but it has not been formally assessed in a clinical trial for BP. We describe the design of the LIBERTY-BP ADEPT trial (NCT04206553) that aims to investigate the efficacy and safety of dupilumab in achieving sustained remission off oral corticosteroids (OCS) in patients with moderate-to-severe BP.

Methods

LIBERTY-BP ADEPT is a global, randomized, double-blind, placebo-controlled, parallel-group study consisting of a 35-day screening period, a 52-week double-blind treatment period, and a 12-week follow-up period. Inclusion criteria include age 18–90 years and

clinical features of BP with a confirmed diagnosis based on histopathology, immunopathology, and serology. Exclusion criteria include previous treatment with IL-4 or IL-13 antagonists or systemic or medium-to-high potency topical corticosteroids within 7 days of the baseline visit. All patients receive standard OCS to control disease activity at the start of the treatment period. Post randomization, after 2 weeks of sustained remission, OCS is to be gradually tapered and discontinued as long as disease control is maintained. The primary endpoint is the proportion of patients achieving sustained remission at Week 36. Key secondary endpoints include total cumulative OCS dose, percent change in weekly average daily Peak Pruritus Numerical Rating Scale (NRS) score, and proportion of patients with improved daily Peak Pruritus NRS score ≥4 from baseline to Week 36.

Results

LIBERTY-BP ADEPT aims to enroll 98 patients; enrollment is ongoing and will include more than 17 sites in Europe.

Conclusions

BP shares pathophysiological pathways with type 2 inflammatory diseases mediated by IL-4 and IL-13. The ongoing LIBERTY-BP ADEPT study is the first randomized, controlled trial designed to evaluate the efficacy and safety of dupilumab in patients with moderate-to-severe BP.

Acknowledgments

Data first presented at the 31st European Academy of Dermatology and Venerology (EADV 2022) Congress; Milan, Italy, September 7-10, 2022. Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifier: NCT04206553. Medical writing/editorial assistance was provided by Corinne Wilson, PhD, and Jessica Olive, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

Disclosures

Murrell DF: Regeneron Pharmaceuticals, Inc. – investigator, advisory board; Principia Biopharma – investigator, advisory board; Argenx – investigator, advisory board; AstraZeneca – investigator; Roche: investigator, advisory board; co-creator of BPDAI.

Joly P: Amgen, Argenx, AstraZeneca, Innovaderm, Principia Biopharma, Roche, Sanofi-Regeneron Pharmaceuticals, Inc., Thermo Fisher Scientific – consultant.

Werth VP: Regeneron Pharmaceuticals, Inc. – honoraria and research grant funding; co-creator of BPDAI.

Laws E, Mannent LP, Dubost-Brama A: Sanofi – employees, may hold stock and/or stock options in the company.

Beazley B, Shabbir A: Regeneron Pharmaceuticals, Inc. − employees and shareholders.