Positive topline Phase 2b data in atopic dermatitis support amlitelimab as a potential first and best-in-class novel investigational anti-OX40-ligand monoclonal antibody

PUBLISHED JUN 26, 2023
BY SANOFI

Positive topline Phase 2b data in atopic dermatitis support amlitelimab as a potential first and best-in-class novel investigational anti-OX40-ligand monoclonal antibody

- Amlitelimab shows statistically significant improvements in signs and symptoms of moderate-to-severe atopic dermatitis in adults

- Study met its primary endpoint of percentage change in Eczema Area and Severity Index score from baseline at 16 weeks, with continued improvement seen through 24 weeks; improvements also seen in key secondary endpoints at 16 and 24 weeks

- 5th positive read-out for Sanofi's pipeline since beginning of 2023

- Data support Sanofi's Immunology strategy built around exploring disruptive mechanisms of action for people living with chronic inflammatory diseases

Paris, June 27, 2023. The primary endpoint was met in a Phase 2b study (STREAM-AD) of amlitelimab in adults with moderate-to-severe atopic dermatitis whose disease cannot be adequately controlled with topical medications or for whom topical medications are not a recommended treatment approach.

In this dose-ranging study, treatment with amlitelimab resulted in statistically significant improvements in average Eczema Area and Severity Index (EASI) score from baseline at 16 weeks compared to

placebo for all four subcutaneous doses that were studied. There were also improvements in key secondary outcome measures and continued improvements were observed through week 24 in primary and key secondary outcomes. Biomarker results support an effect on both type 2 and non-type 2 pathways.

Amlitelimab was well-tolerated in the study across all dose arms and no new safety concerns were identified.

Head of Global Development, Immunology and Inflammation, Sanofi

> While we have made significant strides in the treatment of atopic dermatitis, there are patients who are still in need of new options. We believe that the results from this Phase 2b study with amlitelimab support our perspective that targeting OX40-Ligand has the potential to provide a first and best-in-class treatment option that addresses type 2 and non-type 2 inflammation to meet the individual needs of people living with atopic dermatitis and other chronic inflammatory diseases. We look forward to advancing into a larger Phase 3 clinical development program and continuing to drive momentum in our Immunology pipeline to deliver first or best-in-class treatments.

Amlitelimab is a fully human non-depleting monoclonal antibody that binds to OX40-Ligand, a key immune regulator, and has the potential to be a first-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis and asthma. By targeting OX40-Ligand, amlitelimab aims to restore immune homeostasis between pro-inflammatory and regulatory T cells.

Detailed efficacy and safety results from this trial will be presented in a future scientific forum. Amlitelimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority.

STREAM-AD, a Phase 2b study, was a randomized double-blind, placebo-controlled study, evaluating amlitelimab in adult patients with moderate-to-severe atopic dermatitis whose disease was inadequately controlled with topical therapies or where such therapies were not advisable.

The primary endpoint was percentage change in EASI from baseline

at 16 weeks. Key secondary endpoints included change in EASI from baseline at 24 weeks, percentage of patients with at least a 75% reduction from baseline in EASI at 16 and 24 weeks, percentage of patients with a response of IGA 0 (clear) or 1 (almost clear) and a reduction from baseline ≥ 2 points at 16 and 24 weeks, and proportion of patients with improvement (reduction) of weekly average of pruritus NRS ≥ 4 with a baseline pruritus of ≥ 4 from baseline at 16 and 24 weeks.

The study enrolled 390 people in Australia, Bulgaria, Canada, Czechia, Germany, Hungary, Japan, Poland, Spain, Taiwan, the United Kingdom and the United States.

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

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Sandrine Guendoul | + 33 6 25 09 14 25 | sandrine.guendoul@sanofi.com

Sally Bain | + 1 617 834 6026 |sally.bain@sanofi.com

Victor Rouault | + 33 6 70 93 71 40 |victor.rouault@sanofi.com

Eva Schaefer-Jansen | + 33 7 86 80 56 39 |eva.schaefer-jansen@sanofi.com

Arnaud Delépine | + 33 6 73 69 36 93 |arnaud.delepine@sanofi.com

Corentine Driancourt | + 33 6 40 56 92 21 | corentine.driancourt@sanofi.com

Felix Lauscher | + 1 908 612 7239 |felix.lauscher@sanofi.com

Tarik Elgoutni| + 1 617 710 3587 |tarik.elgoutni@sanofi.com

Nathalie Pham | + 33 7 85 93 30 17 |nathalie.pham@sanofi.com

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listed under “Risk Factors” and

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Press release distributed by Wire Association on behalf of Sanofi, on Jun 26, 2023. For more information subscribe and follow us.

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