News release

Kyowa Kirin Presents Positive Data from Phase 3 Study of LUMICEF® in Systemic Sclerosis at EULAR 2022 Congress

Tokyo, Japan, June 1, 2022 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that positive results from a Phase 3 study of LUMICEF®*1 [KHK4827, generic name: brodalumab (genetical recombination)] for systemic sclerosis*2 were presented at the EULAR (European Alliance of Associations for Rheumatology) 2022 Congress held from June 1 to June 4, 2022.

[Result of Phase 3 Study]

ID: POS0881

Title: Efficacy and safety of subcutaneous brodalumab, a fully human anti–IL-17RA monoclonal antibody, for systemic sclerosis with moderate-to-severe skin thickening: a multicenter, randomized, placebo-controlled, double-blind phase 3 study

Presenter: Takemichi Fukasawa, MD

We reported data from the double-blind comparative period up to 52 weeks of treatment in the phase 3 study that evaluated the efficacy and safety of brodalumab in patients with systemic sclerosis with moderate to severe skin thickening. Brodalumab showed a statistically significant improvement in the primary endpoint, change from the baseline in mRSS*3 at week 24, compared to placebo (-21.2 [95% CI: -23.9, 18.5]; P<0.0001), thus the efficacy of brodalumab was confirmed.

Brodalumab demonstrated a rapid, sustained reduction in mRSS over 52 weeks, and improved or prevented worsening of secondary endpoints compared to placebo.

The incidence of adverse events in the double-blind comparison period was similar in the placebo and brodalumab groups. The safety profile of brodalumab in patients with systemic sclerosis was similar to that previously observed in other diseases such as psoriasis.

The results of the Phase 1 clinical trial were also presented in an e-poster. These abstracts are available on the EULAR Congress website. (link)

[Related Abstract (Results of Phase 1 Study]

ID: POS0857

Title: Pharmacokinetics, safety, and efficacy of subcutaneous brodalumab for systemic sclerosis with moderate-to-severe skin thickening: a single-arm, open-label, multi-dose, phase 1 trial

Presenter: Takemichi Fukasawa, MD

Kyowa Kirin submitted supplemental New Drug Application (sNDA) to Ministry of Health, Labour and Welfare (MHLW) in December 2021 in Japan based on the data from these clinical studies. This sNDA has been under review[*4]

Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin said, "We are very pleased to present data from Phase 3 study of LUMICEF® for systemic sclerosis in EULAR 2022 congress. We would also like to thank the many patients with systemic sclerosis and medical institutions for their cooperation in conducting the clinical studies. A safe, highly effective treatment that can be used for a long time has been desired for the treatment of systemic sclerosis. We highly hope that LUMICEF® would be a drug that can meet unmet medical needs of the patients with systemic sclerosis."

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

***1: About LUMICEF®**

LUMICEF is a fully human anti-interleukin-17 (IL-17) receptor A antibody that inhibits biological activity of inflammatory cytokines such as IL-17A, IL-17A/F, IL-17F, IL-17C by binding to IL-17A receptor selectively. It was approved in Japan in July 2016 for the treatment of psoriasis (psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and psoriatic erythroderma) that respond inadequately to existing therapies. In November 2020, this drug was also approved for the additional indications of ankylosing spondylitis and non-radiographic axial spondyloarthritis.

***2: About systemic sclerosis**

Systemic sclerosis is a chronic disease characterized by sclerosis of skin and internal organs. The progression of the disease and the course of symptoms vary from patient to patient, and its pathogenesis is considered to be related to immune abnormalities, fibrosis, and vascular disorders, but the cause of this disease has not been identified. The number of patients in Japan is estimated to be more than 20,000, and it is positioned as a designated intractable disease (designated intractable disease 51).

***3: About mRSS (Modified Rodnan total skin thickness score)**

This score is a semi-quantitative method of assessing skin stiffness by palpation, dividing the body into 17 areas and scoring the degree of skin stiffness in each area on a 4-point scale (0-3), with the sum of the scores used as the skin score. mRSS is considered to be the most useful index for evaluating the effect of treatment on skin sclerosis because it reflects pathological fibrotic changes in the skin and is consistent with disease activity.

***4: About the NDA submission in December 2021**

For more information, please visit the website below.
https://www.kyowakirin.com/media_center/news_releases/2021/e20211215_01.html