

News release

Kyowa Kirin Presents Positive Data from Phase 3 Study of LUMICEF® in Palmoplantar Pustulosis at EADV 2022 Congress

Tokyo, Japan, September 7, 2022 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that positive data from a phase 3 study of LUMICEF®*1 [KHK4827, generic name: brodalumab (genetical recombination)] for palmoplantar pustulosis (PPP) *2 will be presented at the European Academy of Dermatology and Venereology (EADV) 2022 Congress. The abstract of this presentation is available on EADV website ([link](#)).

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Title: Efficacy and Safety of Brodalumab, An Anti-interleukin-17 Receptor A Monoclonal Antibody, in Japanese Patients with Palmoplantar Pustulosis: 16-Week Results of a Phase 3, Multicenter, Randomized, Double-blind, Placebo-Controlled Study

The phase 3, multicenter, randomized, double-blind, placebo-controlled trial investigated the efficacy and safety of brodalumab in PPP patients with inadequate response to existing treatments. The efficacy of brodalumab was verified with statistically significant improvement in primary endpoint which was the change from baseline in PPPASI*3 total score at week 16, compared to placebo (brodalumab vs placebo group: 13.73 [95% CI: 10.91, 16.56] vs 8.45 [95% CI: 5.76, 11.13], P=0.0049).

Brodalumab also demonstrated the trend toward improvement in many of the secondary efficacy endpoints compared to placebo.

The more common adverse events in the double-blind comparison period observed in brodalumab than placebo group were otitis externa, folliculitis and so on. Brodalumab was found to be tolerable with few serious or severe events occurring.

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 PPP in the EADV meeting. We would also like to thank many patients with PPP and medical institutions for their cooperation in conducting the clinical study. Symptoms in the palms and soles of the hands and

feet interfere with PPP patients' daily lives, so new therapeutic treatments are desired to improve their quality of life. We really hope that LUMICEF[®] would be a drug that can meet unmet medical needs of the patients with PPP.”

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 PPP**

PPP is a refractory skin disease characterized by recurrent aseptic blisters and pustules on the palms and soles. It is known that PPP patient's quality of life tends to be impaired due to its conspicuousness and the pain and itchiness with palmoplantar symptoms and arthralgia.

***3: About PPPASI (PPP Area and Severity Index)**

PPPASI is a scale for grading the area and severity of PPP lesions.