News release

Kyowa Kirin Announces Application for Partial Change of Approved Indication of LUMICEF® for Palmoplantar Pustulosis in Japan

Tokyo, Japan, September 15, 2022 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company has filed an application to the Japanese Ministry of Health, Labour and Welfare for partial change of approved indication of LUMICEF®*1 [KHK4827, generic name: brodalumab (genetical recombination)] for palmoplantar pustulosis (PPP) *2 in Japan on September 15th.

This supplemental application is based on the results of a Phase 3 clinical trial of brodalumab in patients with PPP who have had an inadequate response to existing therapies in Japan. LUMICEF® met the primary endpoint, and efficacy and safety in patients with PPP were confirmed in this study.

Yoshifumi Torii, Ph.D, Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin said, "We are profoundly pleased to submit LUMICEF® as the first IL-17 pathway inhibitor to treat PPP. 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 palmoplantar pustulosis (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 the results of Phase 3 clinical trial**

Phase 3 clinical trial results were presented at the European Congress of Dermatology and Venereology (EADV) in September 2022. For more information, please visit the website below.
https://www.kyowakirin.com/media_center/news_releases/2022/pdf/e20220907_01.pdf