

News release

Kyowa Kirin Received Partial Change Approval of LUMICEF[®] for Palmoplantar Pustulosis in Japan

Tokyo, Japan, August 23, 2023 --Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces that the company has received approval from the Ministry of Health, Labour and Welfare ("MHLW") for partial change of approved indication of LUMICEF[®]*1[KHK4827, generic name: brodalumab (genetical recombination)] for the treatment of palmoplantar pustulosis*2 (PPP) that respond inadequately to existing therapies.

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. LUMICEF[®] is the first IL-17 pathway inhibitor approved in PPP.

This approval 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. In September 2022, Kyowa Kirin filed an application for partial change of approved indication of LUMICEF[®]. Phase 3 clinical trial results have been presented at the Congress of European Academy of Dermatology and Venereology (EADV) in September 2022 and will be presented at the Annual Meeting of the Japanese Society of Psoriasis Research in August 2023.

Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin said, "Because the conspicuousness, the pain and itchiness with palmoplantar symptoms, and arthralgia interfere with daily life, new therapeutic treatments are desired to improve their quality of life. We are pleased that LUMICEF[®] will contribute to PPP patients as a new treatment option with this approval."

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® 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 that respond inadequately to existing therapies.

***2: About Palmoplantar Pustulosis**

Palmoplantar Pustulosis is a refractory skin disease characterized by recurrent aseptic pustules on the palms and soles.