# News release

## Kyowa Kirin Submitted Partial Change Approval Application of LUMICEF® in Japan

Tokyo, Japan, January 8, 2020 ---Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces today that it has submitted a supplemental application for LUMICEF® (code name: KHK4827, generic name: brodalumab (genetic mutation)) [*1] for the treatment of axial spondyloarthritis (axSpA)[*2].

The supplemental application is based on the result of a phase 3 clinical trial[*3] in patients with axSpA（Ankylosing Spondylitis and Non-radiographic axSpA）in Japan, South Korea and Taiwan. LUMICEF met the primary endpoint, and efficacy and safety in patients with axSpA were confirmed in this study.

"Submitting this application for LUMICEF for axial spondyloarthritis is a significant step," said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Kirin. "We believe that LUMICEF has the potential to contribute to the health of patients with axSpA."

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 IL-17A, IL-17F and other IL-17s. Brodalumab has been approved in Japan in July 2016 for psoriasis (psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and psoriatic erythroderma) that respond inadequately to existing therapies.

***2: About Axial Spondyloarthritis (axSpA)**

Axial spondyloarthritis, which characterized by predominant involvement of the chronic enthesitis of the spine and/or sacroiliac joints, include ankylosing spondylitis and non-radiographic axial spondyloarthritis.

***3: About the Phase 3 Clinical Trial**

A Phase 3, multi-regional, randomized, double-blind, placebo-controlled study in order to evaluate the efficacy and safety of brodalumab in patients with axSpA. The primary efficacy endpoint, the percentage of axSpA subjects who achieved ASAS40 at Week 16, was 43.8% in the brodalumab group and 24.1% in the placebo group, and significantly higher in the brodalumab group than in the placebo group ($p<0.05$).