News release

Kyowa Kirin Announces Partial Change Approval of LUMICEF® for the Treatment of Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis in Japan

Tokyo, Japan, November 27, 2020 -Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces today that LUMICEF® (code name: KHK4827, generic name: brodalumab (genetic mutation)) was granted the supplemental approval for the treatment of ankylosing spondylitis (AS)[*1] and non-radiographic axial spondyloarthritis (nr-axSpA)[*2] in Japan.

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 the treatment of psoriasis (psoriasis vulgaris, psoriatic arthritis, pustular psoriasis, and psoriatic erythroderma) that respond inadequately to existing therapies.

This supplemental approval is based on the result of the efficacy and safety of brodalumab confirmed in the phase 3 clinical trial[*3] in patients with axial spondyloarthritis (axSpA).

"In Japan, AS and nr-axSpA are still with very high unmet medical needs." said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. "With the approval, I'm delighted that our effort on providing more medical solutions paid off."

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 ankylosing spondylitis**

Axial spondyloarthritis is characterized by chronic inflammatory back pain and causes unexplained enthesitis predominantly in the sacroiliac joints and/or the spine. Ankylosing spondylitis is classified as a disease with sacroiliac joint findings that meets X-ray criteria in axial spondyloarthritis.

***2: About non-radiographic axial spondyloarthritis**

Non-radiographic axial spondyloarthritis is classified as a disease with no sacroiliac joint findings that meets X-ray criteria in 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 (AS and nr-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 ($p<0.05$). No remarkable safety concerns were identified in the safety assessment up to 68 weeks of administration.