Kyowa Hakko Kirin Announces Initiation of Global Phase 3 Study of KHK4827 (Brodalumab) in Patients with Axial Spondyloarthritis (axSpA)

Tokyo, Japan, April 24, 2017--- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") today announces the initiation of a global Phase 3 clinical study evaluating KHK4827 (brodalumab) for Axial Spondyloarthritis (axSpA).

The Phase 3 study is a multi-regional, randomized, double-blind, placebo-controlled study in Japan, South Korea and Taiwan, to evaluate the efficacy and safety of brodalumab (subcutaneous injection) in patients with axSpA (ankylosing spondylitis and non-radiographic axial spondyloarthritis).

The Kyowa Hakko 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.

Outline of this study

Target Disease	Axial Spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis)
Phase	Phase 3
Design	Multi-regional, Randomized, Double-blind, Placebo-controlled Study with an Open Label Extension Study
Administration Group	KHK4827(brodalumab), placebo
Location	Japan, South Korea, Taiwan

About Axial spondyloarthritis

Axial spondyloarthritis, which characterized by predominant involvement of the chronic enthesitis of the spine and/or sacroiliac joints, include ankylosing spondylitis with sacroiliitis detected by X-ray radiography and non-radiographic axial spondyloarthritis without radiographic sacroiliitis.

About KHK4827 (brodalumab)

Brodalumab 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.