Toyama Chemical Co., Ltd. Eisai Co., Ltd.

Toyama Chemical and Eisai Submit Marketing Authorization Application for Anti-Rheumatic Agent T-614

Toyama Chemical Co., Ltd. (Headquarters: Tokyo, President: Masuji Sugata, "Toyama Chemical") and Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that they have submitted a marketing authorization application (MAA) for T-614 (iguratimod), an anti-rheumatic agent being jointly developed in Japan by the two companies.

Toyama Chemical and Eisai are developing T-614 based on a co-development and license agreement they concluded in 1998. If and when approved, Taisho Toyama Pharmaceutical Co., Ltd. and Eisai will co-promote the agent under a two-brand, two-channel scheme.

T-614 is a novel disease modifying anti-rheumatic drug (DMARD) originally discovered by Toyama Chemical. An MAA for the agent was previously submitted in 2003, however, after it was determined that data concerning the efficacy and safety of its use as an add-on to standard therapies was necessary, the application was temporarily withdrawn in 2009 in order to conduct an additional clinical study.

The additional clinical study conducted in Japan was a double-blind, placebo-controlled study in rheumatoid arthritis patients who did not achieve satisfactory effects with methotrexate ("MTX") alone. Patients treated with T-614 in combination with MTX demonstrated favorable tolerability, as well as significant improvements compared to those treated with placebo (MTX-only arm) in the study's primary endpoint of ACR20 response rate at Week 24. The two companies have resubmitted the MAA as the study confirmed with statistical significance the efficacy of the agent as an add-on therapy for use with MTX, the standard of care.

Toyama Chemical and Eisai will offer T-614 as a new option for use in the pharmacological treatment of rheumatoid arthritis and believe they can make further contributions to address the diversified needs of, and increase the benefits provided to, rheumatoid arthritis patients.

[Please refer to the following notes for a glossary of terms]

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[Notes to Editors]

Glossary of Terms

1. Rheumatoid Arthritis

Rheumatoid arthritis is a disease that leads to inflammation of multiple joints throughout the body, causing joint swelling and pain. Progression over the long-term also causes joint degeneration and functional impairment. While the cause of rheumatoid arthritis is unknown, microorganisms or some other cause are thought trigger the proliferation of synovial cells, which line the inner surface of the joint cavity. Furthermore, this process causes an increase in the number of blood vessels in joints, and migration of lymphocytes, macrophages and other types of white blood cells from joint blood vessels to the synovial tissue in joints. An immune-reaction occurs in localized joints, causing an inflammatory reaction and the progression of cartilage and bone destruction due to the effects of cytokines produced by lymphocytes and macrophages.

2. Disease Modifying Anti-Rheumatic Drugs (DMARDs)

DMARDs (Disease Modifying Anti-Rheumatic Drugs) are a category of drugs defined by their use in rheumatoid arthritis to slow disease progression. They are expected to control the immune abnormalities that are thought to cause inflammation in rheumatoid arthritis. Major DMARDs currently available in Japan include methotrexate, salazosulfapyridine and bucillamine.

3. ARC20 Response Rate

ACR20 is a criterion developed by the American College of Rheumatology that measures improvement in clinical symptoms of rheumatoid arthritis. It expresses the percentage of patients who demonstrated a 20% or greater improvement in tender and swollen joint counts and at least three of the following five disease activity variables: patient's assessment of pain, patient's assessment of global disease activity, physician's assessment of global disease activity, patient's assessment of physical function, and chronic response protein (CRP) or erythrocyte sedimentation rate (ESR) concentrations.