



August 17, 2017

Notice of the Start of a Japanese Phase 2/3 Clinical Study of the Anti-NGF Antibody MT-5547 in Osteoarthritis

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director; Masayuki Mitsuka; hereafter, "MTPC") announced today that it has initiated a Japanese phase 2/3 clinical study (Study J01) of the fully human anti-NGF (nerve growth factor) monoclonal antibody MT-5547 (generic name: fasinumab) in patients with osteoarthritis.

This study is a placebo-controlled, randomized, double-blind, comparative study to verify the efficacy and safety of the use of MT-5547 in patients who have moderate or severe pain due to osteoarthritis of the knee or hip. The therapeutic efficacy of MT-5547 for the relief of pain due to osteoarthritis will be evaluated by a comparison versus placebo in the change from baseline at Week 16 in the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) pain score, the primary efficacy endpoint.

MT-5547 is an anti-NGF antibody that MTPC has licensed from Regeneron, which is headquartered in New York. On September 29, 2015, MTPC signed a licensing agreement with Regeneron granting MTPC the exclusive rights to develop and market MT-5547 in Japan, Korea and nine other Asian countries, excluding China.

MTPC's goal is to obtain 10 late-stage development products within the period covered by MTPC's Medium-Term Management Plan 16-20: Open Up the Future, in order to reach one of the four strategic priorities. One of those priorities is "Maximizing Pipeline Value." MT-5547 became a late-stage development product in 2017. Osteoarthritis is a disease for which there is a need for new treatments that provide effective pain relief in patients who have exhausted or are inappropriate for existing therapies coupled with a safety and tolerability profile that mitigates the concerns associated with existing therapies. MTPC continues to proactively develop new products that can satisfy unmet medical needs in strategic therapeutic areas.

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Reference

Osteoarthritis

Osteoarthritis is a disease in which cartilage in the joints wears down, resulting in pain and/or swelling in the knees, hips, hands, feet, or spine. In osteoarthritis, the bone underneath the cartilage hardens, resulting in the formation of bone spurs and in deformation of the joint. As symptoms progress, joint movement may also become increasingly limited.

MT-5547

MT-5547 (fasinumab) is a fully human antibody that is being investigated for its potential to relieve pain in certain patients. MT-5547 binds to NGF (nerve growth factor), which is secreted when pain is produced, and inhibits the effects of NGF. MT-5547 was discovered by Regeneron (REGN475) and is being developed in the West as a therapeutic medication for osteoarthritis pain and chronic low back pain.