May 25, 2020

Regulatory Approval of Thailand for Marketing Teneligliptin (MP-513), a treatment agent for type 2 diabetes mellitus

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Chuo-ku, Osaka; President & Representative Director, CEO: Hiroaki Ueno), announced today that MTPC's subsidiary in Thailand obtained the regulatory approval of TENELIA® (generic name; teneligliptin hydrobromide hydrate; Japan name: TENELIA® 20mg tablets) for a treatment agent for type 2 diabetes mellitus from Food and Drug Administration Thailand on April 7th, 2020, following the completion of the approval application procedure.

In Japan, approval for teneligliptin was received in June 2012, in April 2014 in Korea. Thailand is the third country that has approved teneligliptin.
In Thailand, Mitsubishi Tanabe Pharma (Thailand) Co., Ltd., the locally based subsidiary of MTPC, will market as the Marketing Authorization Holder (MAH) teneligliptin under the name TENELIA®.

TENELIA®, originating in Japan, is a dipeptidyl peptidase-4 (DPP-4) inhibitor discovered by MTPC. TENELIA® has made it highly effective in lowering each of the postprandial blood glucose levels, as well as fasting blood glucose levels, with once-a-day administration. TENELIA® needs no dose adjustments according to the levels of renal or hepatic dysfunction, so that TENELIA® can be used to treat a wide range of patients with diabetes.

MTPC filed teneligliptin to Asian countries including China and is working to get early approval to bring this product to patients as soon as possible.
By providing a new option for the treatment of diabetes to a growing number of patients in the world, MTPC shows its continued resolve to improve their quality of life (QOL).

Mitsubishi Tanabe Pharma Corporation
Corporate Communications Department
Media contacts: TEL: +81 6 6205 5119

<Reference>

■ Teneligliptin（Japan name: TENELIA® 20 mg tablets）

In Japan, approval for TENELIA (generic name: teneligliptin hydrobromide hydrate, Japan name: TENELIA® 20 mg tablets), a treatment agent for type 2 diabetes mellitus, was received in June 2012, with approval for a partial change in its indication received in December 2013. In Korea, approval for use of TENELIA in combination with biguanide agents was received in April 2014. Teneligliptin was filed to Asian countries including China.

■ Mitsubishi Tanabe Pharma (Thailand) Co., Ltd.

Mitsubishi Tanabe Pharma (Thailand) Co., Ltd. was founded as a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC) in Thailand in 2016. In Thailand, which has one of the largest pharmaceutical market in ASEAN region, the company sells drugs for cardiovascular diseases, such as HERBESSER®. The company will also be marketing those products approved in Thailand.