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ASIA EDITION

# Milestone drug approvals on a single day pave way for new therapies in Japan

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September 28th witnessed the Japanese Ministry of Health, Labour and Welfare (MHLW) granting approvals to many drugs aimed at treating important medical conditions in Japan.

With Merck's diabetes drug approval, Japan becomes the first country to sell MARIZEV, which offers an important option for people in Japan to manage their type 2 diabetes, particularly for those who prefer once-weekly dosing.

Multiple sclerosis (MS) is an autoimmune disease, the cardinal sign of which is inflammatory demyelination of the central nervous system characterized by demyelinating plaques in the brain and the spinal cord. The morbidity in patients with MS is estimated to be approximately 18,000 in Japan, and its prevalence shows an increasing trend. The approval of Takeda's Copaxone Subcutaneous Injection (developed by Teva Pharmaceutical Industries) marks an important milestone in the treatment options for MS.

Japan has one of the highest rates of hepatitis C infection in the industrialized world, with approximately 1.5 to 2 million people living with HCV. The approval of Enanta-AbbVie's VIEKIRAX will now offer HCV patients in Japan an all-oral, once daily treatment option that has demonstrated high cure rates in trials.

House dust mites (HDM) are the most common cause of allergy in the world. In Japan, an estimated 25-35 million people suffer from allergy caused by Japanese cedar tree pollen or house dust mites. The approval of Torii's HDM SLIT-tablet now

will be a relevant treatment option for Japanese patients suffering from allergies caused by house dust mites.

**Takeda's Copaxone Subcutaneous Injection**

Takeda Pharmaceutical Company Limited has obtained the New Drug Application approval for Copaxone Subcutaneous Injection 20 mg Syringe (generic name: glatiramer acetate) for the treatment of multiple sclerosis, from the Japanese Ministry of Health, Labour and Welfare.

Developed by Teva Pharmaceutical Industries Ltd. (Teva), Copaxone is a subcutaneous injection administered once daily to prevent the relapse of multiple sclerosis. Copaxone is one of the most frequently-used drugs in multiple sclerosis therapy and is approved in more than 50 countries worldwide.

In Japan, glatiramer acetate was developed as an Unapproved New Drug by Teva Pharmaceutical K.K., a wholly owned subsidiary of Teva, at the request of the Japanese Ministry of Health, Labour and Welfare. In March, 2013, Takeda and Teva signed a licensing agreement in which Teva granted Takeda the right to commercialize glatiramer acetate in Japan. Takeda submitted the NDA in December 2014 under the terms of this agreement.

The approval is based on the safety and efficacy results of an open-label, 52-week clinical trial conducted in Japan by Teva Pharmaceutical K.K. in patients with relapsing-remitting multiple sclerosis as well as 3 clinical trials from overseas conducted by Teva in patients with relapsing-remitting multiple sclerosis.

This approval in Japan represents an extremely important milestone for Takeda, and we expect that this drug, which is the first-line therapy overseas for relapsing-remitting multiple sclerosis, can contribute to the therapy of Japanese patients with multiple sclerosis. We will continue to make efforts to deliver drugs that are needed by patients and healthcare professionals.

**Merck's type 2 diabetes drug MARIZEV, Approved in Japan**

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has approved Merck's MARIZEV (omarigliptin) 25 mg and 12.5 mg tablets, an oral, once-weekly DPP-4 inhibitor indicated for the treatment of adults with type 2 diabetes. Japan is the first country to have approved omarigliptin.

The approval of MARIZEV in Japan is based on Phase 3 trials of Japanese patients. The worldwide clinical development program for omarigliptin, O-QWEST (Omarigliptin Q Weekly Efficacy and Safety in Type 2 Diabetes), includes 10 phase III clinical trials involving approximately 8,000 patients with type 2 diabetes. Merck plans to submit omarigliptin for regulatory approval in the United States by the end of 2015. Other worldwide regulatory submissions will follow. The trademark for omarigliptin in other countries has not yet been announced.

**Torii's house dust mite SLIT-tablet**

The Japanese Ministry of Health, Labour and Welfare has approved the New Drug Application for the house dust mite (HDM) sublingual allergy immunotherapy (SLIT) tablet MITICURE, developed by Copenhagen-based ALK. MITICURE is the Japanese trade name of the HDM SLIT-tablet licensed by ALK to Torii for Japan. MITICURE is indicated in adults and adolescents (12-64 years) as hypo-sensitization therapy (allergy immunotherapy) for the treatment of allergic rhinitis caused by house dust mites.

In parallel with the approval, Torii also announced that it is initiating a new clinical phase III trial to investigate the safety and efficacy of MITICURE in pediatric patients (5-11 years). The trial is expected to enroll approximately 400 subjects.
ALK's partnership with Torii covers the development, registration and commercialization of two sublingual allergy immunotherapy tablets for Japan.

MITICUREÃ?Â is the first of these products to be approved and, following today's approval, Torii will move ahead with its launch plans once a price for MITICURE has been set under Japan's National Health Insurance system. A regulatory submission of the second product, a SLIT-tablet against Japanese cedar pollen allergy, is currently being prepared following the successful completion of a phase II/III clinical trial earlier this year. The Japanese approval of MITICURE entitles ALK to a milestone payment from Torii. Consequently, ALK is adjusting its 2015 financial outlook upwards.

**Enanta-AbbVie's chronic Hepatitis C VIEKIRAX**

Enanta Pharmaceuticals Inc. has announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved AbbVie's VIEKIRAX (ombitasvir/paritaprevir/ritonavir), as a new interferon-free and ribavirin-free treatment option for adult patients in Japan with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection, including those with compensated liver cirrhosis. VIEKIRAX consists of two-direct-acting antiviral (2-DAA), fixed-dose tablets containing paritaprevir/ritonavir with ombitasvir. VIEKIRAX is approved in Japan using once daily dosing for 12 weeks for GT1 HCV patients.

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the two DAAs in AbbVie's VIEKIRAX.
Enanta expects to earn and receive a $30 million milestone payment in the quarter ending December 31, 2015 upon price reimbursement approval of VIEKIRAX in Japan. In addition, 45% percent of AbbVie's net sales of the 2-DAA regimen in Japan will be included in the worldwide paritaprevir net sales on which Enanta is eligible to receive annually tiered royalties, ranging from the low double digits up to twenty percent.

AbbVie is responsible for all worldwide development and commercialization of VIEKIRAX and other HCV treatment regimens containing paritaprevir. Paritaprevir/ritonavir and ombitasvir, AbbVie's NS5A inhibitor, are also included in AbbVie's 3-DAA VIEKIRA PAK regimen, which was approved in the U.S. in late 2014 for patients with GT1 HCV infection. VIEKIRAX was first approved under that name in Europe in January 2015.

In April 2015, the Japanese MHLW granted AbbVie priority review for VIEKIRAX on the basis of clinical usefulness of the treatment and recognizing the severity and unmet need of HCV in Japan.