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Development Status of ONO-2506 for Injection/PROGLIA outside Japan and Development Plan of Compounds in-licensed from Merck in Japan

1. *Development Status of ONO-2506 for Injection/PROGLIA for Acute Ischemic Stroke outside Japan*

On December 29th 2004, Ono Pharmaceutical Co., Ltd. ("Ono") announced the results of a Japanese Phase IIb clinical study conducted in Japan for ONO-2506 for Injection/PROGLIA, which is under development for acute ischemic stroke both in and outside Japan.

A Phase II clinical study with about 1300 acute ischemic stroke patients is underway in North America, and over 800 patients have already been enrolled for the study. A Data Safety Monitoring Board ("DSMB") meeting is to be held to make an interim analysis and explore whether it is appropriate to continue the study. Although the DSMB meeting was originally planned for January, it will be postponed for a couple of months. The overall study plan will not be affected by this slight delay of the interim analysis, since the remaining patient enrollment for the study is ongoing.

When the DSMB meeting is held and the recommendation from the DSMB is made, Ono will make an announcement about the interim analysis.

(Reference)

Interim Analysis by Data Safety Monitoring Board

The DSMB consists of experts in medical and statistical fields who are not directly involved in the clinical study. The Board will examine the safety and efficacy data from the study and make a recommendation to the sponsor of the study whether the study should be continued. Under the DSMB process, the sponsor receives only a recommendation on the study continuation and does not have access to the study data.

Profile of Compound

ONO-2506 for Injection/PROGLIA

This compound was discovered by Ono and is now under development for the treatment of acute ischemic stroke both in and outside Japan. ONO-2506 is believed to modulate the function of astrocytes, a kind of glial cell in the brain, and to inhibit expansion of cerebral infarction, thereby alleviating the effects of acute cerebral infarction. Based on preclinical data, it is anticipated that the drug will show efficacy even when administered several hours after the onset of cerebral infarction, and also that there is no risk of cerebral hemorrhage since this drug has no action on the blood coagulation system.

ONO-2506 for Injection has a novel mechanism of action, and early studies suggest its potential as a neuroprotective agent. In contrast, t-PA (tissue plasminogen activator), a thrombolytic and the only drug launched for acute ischemic stroke in the US and Europe, is judged to be effective and approved only when administered within 3 hours from the onset of cerebral infarction and has a risk of bleeding.

Under the license agreement with Merck & Co. Inc. ("Merck") that was concluded in November 2004, Ono out-licensed ONO-2506 for Injection to Merck granting them worldwide development and marketing rights (excluding Japan, South Korea and Taiwan).

2. Development Plan of Compounds in-licensed from Merck in Japan

In connection with the license, Ono also in-licensed MK-0431, an investigational anti-diabetic agent, and MK-0869, an investigational agent for the prevention of chemotherapy-induced nausea and vomiting. MK-0431 will be co-developed and co-marketed by Ono with Banyu Pharmaceutical Co., Ltd. ("Banyu"), a subsidiary of Merck, in Japan. Ono will develop, register and commercialize MK-0869 on an exclusive basis in Japan.

The first meeting among Ono, Merck and Banyu to discuss the development plan in Japan for these in-licensed compounds (ONO-5435 / MK-0431 and ONO-7436 / MK-0869) resulted in substantive, collaborative discussions.

ONO-5435 (MK-0431) is currently in Phase II development in Japan and is being developed by Banyu. Ono will participate with Banyu in Phase III development in Japan.

ONO-7436 (MK-0869), an investigational anti-emetic being studied for use in combination with other anti-emetic agents for the prevention of nausea and vomiting associated with cancer chemotherapy, has already completed Phase I studies under Banyu. Ono will assume responsibility for the development from Phase II. The Phase II study is in preparation and will commence this spring.

(Reference)

Profile of Compounds

ONO-5435 (MK-0431)

This is a DP-IV (dipeptidyl-peptidase IV) inhibitor, an investigational oral anti-diabetic developed by Merck and is expected to be useful for control of postprandial hyperglycemia with low liability for hypoglycemia and/or weight gain in diabetes patients. Merck is conducting Phase III studies outside Japan.

ONO-7436 (MK-0869)

Ono-7436 (MK-0869) is the first NK1 (neurokinin 1) antagonist in the world. It was created by Merck and was launched in the US in April 2003 for the prevention of nausea and vomiting caused by highly emetogenic chemotherapy. The sales in 2004 reached $ 47 million. At present, the drug is sold in 36 countries around the world. Although conventional drugs are effective for acute phase of chemotherapy-induced nausea and vomiting, there are no drugs approved for delayed symptoms (24 hours or later after start of chemotherapy) in Japan. When used in combination with other anti-emetic medicines, the efficacy of the drug for both acute and delayed phases of nausea and vomiting caused by chemotherapy has been confirmed outside Japan and will be examined in Japanese clinical studies.