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Public Relations

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Ono and Merck in Product Licensing Arrangements

Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Kimiichiro Matsumoto) announced today that the company signed an agreement with Merck & Co., Inc. (Headquarters: Whitehouse Station, New Jersey, the US; Chairman: Raymond V. Gilmartin) to out-license ONO-2506 (injectable formulation), a novel compound originally synthesized and developed by Ono for the treatment of acute stroke. Under this arrangement, Ono will receive rights to MK-0431, a new oral anti-diabetic, and to aprepitant (MK-0869) for the treatment of cancer chemotherapy-induced nausea and vomiting from Merck.

Ono granted Merck an exclusive license for development and marketing of ONO-2506 (injectable formulation) and its backup compound in countries around the world (excluding Japan, South Korea and Taiwan). Under the terms of the agreement, Ono will receive an initial payment and milestone payments in addition to royalties on net sales of ONO-2506 (injectable formulation). If Merck obtains additional indications and/or products under the license, Ono will receive additional milestone payments. Ono will supply the drug to Merck as unpackaged product.

In connection with the license, Merck grants Ono co-development and co-marketing rights to MK-0431 (in Phase III stage outside Japan and Phase II in Japan), which is also to be developed and marketed by Banyu Pharmaceutical Co., Ltd., Merck's subsidiary in Japan. In addition, Ono will be granted exclusive rights to develop and market in Japan aprepitant (product name: EMEND, marketed in the US since April 2003 and now in more than 20 countries around the world; Phase I clinical studies completed for Japanese development). Merck will supply MK-0431 and aprepitant to Ono as unpackaged product and finished product, respectively.

Through these agreements Ono aims to maximize the market share of ONO-2506 (injectable formulation), its international strategic product, in the global market, and to mitigate development risks by in-licensing advanced-stage products. Merck has been making prominent efforts to increase its global business through strategic tie-ups to capitalize on its capabilities in R&D and sales. These arrangements recognize and capitalize on the complementary nature of the parties' strategies.

(Reference materials)

Profile of each compound

ONO-2506 (injectable formulation)

This compound was created by Ono and is now under development for the treatment of acute stroke in Japan and North America. ONO-2506 (injectable formulation) is believed to modulate the function of astrocytes, a kind of glial cell in the brain, and, through this new mechanism of action, to inhibit expansion of cerebral infarction, thereby alleviating the effects of acute stroke. 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 it is anticipated that there is no risk of cerebral hemorrhage since this drug has no action on the blood coagulation system. t-PA (tissue plasminogen activator), the only drug launched for acute 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.

The Japanese Phase IIb study for ONO-2506 (injectable formulation) just completed at the end of October and currently under data analysis which is to be completed by the end of this year. ONO-2506 (injectable formulation) is in Phase II stage in North America at present. Overseas development including Phase III clinical study and successive studies outside Japan will be conducted by Merck.

MK-0431

This is a DP-IV (dipeptidyl-peptidase IV) inhibitor, a new oral anti-diabetic created by Merck, which is expected to be useful for control of postprandial hyperglycemia with low/no risks of hypoglycemia and/or weight gain in diabetes patients.

MK-0431 is in Phase III stage outside Japan. Banyu is currently conducting Phase II clinical studies for the drug in Japan, where Ono and Banyu will co-develop and co-market it.

Aprepitant / MK-0869

This is the first NK₁ (neurokinin 1) antagonist in the world created by Merck. Aprepitant was launched in the US market in April 2003 for the treatment of chemotherapy-induced nausea and vomiting. The sales in 2003 reached \$ 27 million (approx. 3 billion yen). At present, the drug is sold in more than 20 countries around the world. Although conventional drugs are effective for acute phase of chemotherapy-induced nausea and vomiting, there are no drugs approved for prolonged symptoms (24 hours or later after start of chemotherapy) in Japan. The efficacy of aprepitant for both acute and prolonged phases of nausea and vomiting has been confirmed outside Japan, and is expected to be confirmed in Japanese trials. At present, Phase I clinical studies are complete for Japanese development, and Ono will continue the development of the drug to obtain approval from the Japanese authority.

*Comments from Merck

Mr. David W. Anstice, President of Human Health for Merck said: "We are delighted to be partnering with Ono, which has an outstanding record in Japan for discovering and commercializing innovative medicines. Merck recognizes the valuable scientific medical achievements being made in Japan today and is committed to working with Ono to bring the benefits of their research to patients globally."

Dr. Peter S. Kim, President of Merck Research Laboratories (R&D department of Merck) said: "We believe intravenous ONO-2506 has the potential to be a new therapeutic option for doctors in the treatment of stroke, a leading global killer and major cause of severe disability. We are delighted about our agreement with Ono, which has earned a global reputation for its leadership in the development of novel new drugs."

*Comments from Ono

Dr. Shozo Matsuoka, Executive Director of Development Headquarters at Ono said: "We expect that ONO-2506 (injectable formulation), a novel drug based on a brand-new concept, will offer an innovative treatment for stroke. The arrangement with Merck, a leading global pharmaceutical company with deep expertise in development and marketing of drugs, is a major step forward for worldwide development of ONO-2506 (injectable formulation) and its early introduction to the global market in the future. We are very much pleased about the partnership with Merck."