ONO PHARMACEUTICAL CO., LTD.

President and Representative Director: Gyo Sagara,

Code No.: 4528 at the 1st section of the Tokyo / Osaka Stock Exchange

INQUIRIES: Kinya Morimoto, Executive Officer, Director, Corporate Communications

Ono to Enter into License Agreements with Merck KGaA

- Development and commercialization by Merck of ONO-4641 for the treatment of multiple sclerosis, worldwide except Japan, Korea and Taiwan
- Co-development and co-marketing of Stimuvax[®], a cancer immunotherapy, in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President and Representative Director: Gyo Sagara) announced today that the company signed two separate agreements with Merck KGaA (Darmstadt, Germany) on October 3, 2011 to out-license ONO-4641, a novel compound originally discovered and developed by Ono for the treatment of multiple sclerosis and to license for co-development and co-marketing Stimuvax® (candidate for product name) in Japan, a novel cancer immunotherapy, globally developed by Merck Serono, the biopharmaceutical division of Merck KGaA. Please refer to the following explanations about details of the agreements.

About out-licensing agreement on ONO-4641

Ono granted Merck an exclusive license for development and commercialization of ONO-4641 in countries around the world except Japan, Korea and Taiwan. Under the terms of the agreement, Ono will receive 1.5 billion yen as an upfront payment. In addition, Ono will also receive milestone payments based on development stage as well as sales-based ones upon achievement of projected sales of ONO-4641.

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist, and the multi-national phase II study, DreaMS * is on-going for the treatment of multiple sclerosis. The drug keeps lymphocytes in lymph nodes and thereby inhibits the infiltration of lymphocytes into lesions. The compound is therefore expected to be a drug for the treatment of auto-immune diseases such as multiple sclerosis, which is regarded as an intractable disease.

* <u>DreaMS</u>: <u>Drug Research EvaluAtion for Multiple Sclerosis</u>

About license, co-development and co-marketing agreement on Stimuvax[®] in Japan

One obtained rights to co-develop and co-market Stimuvax[®] (BLP25 liposome vaccine) in Japan together with Merck. Under the terms of the agreement, One will pay to Merck 5 million euros as an upfront payment.

A Phase II study for Stimuvax[®] (EMR63325-009) is being conducted by Merck Serono Co., Ltd., a Japanese subsidiary of Merck KGaA, for the treatment of non-small cell lung cancer in Japan (Phase III studies are in progress outside Japan). Merck KGaA obtained the exclusive worldwide licensing rights from Oncothyreon Inc., Seattle, Washington, USA. Stimuvax[®] is a cancer immunotherapy targeting the tumor antigen, MUC-1.

"We are very glad to partner with Merck Serono for the development and marketing of ONO-4641, given Merck Serono's commitment to developing treatments for people living with multiple sclerosis," said Gyo Sagara, Ono's President and Representative Director. "Moreover, we are delighted to collaborate in Japan on Stimuvax and together with Merck Serono to offer a potential future medicine for people suffering from non-small cell lung cancer."

"Merck Serono is committed to building on our leadership franchise in multiple sclerosis and we are excited about adding a potential oral treatment, ONO-4641, to our pipeline," said Dr. Stefan Oschmann, President of Merck Serono. "We also believe that Ono will bring a wealth of experience in developing innovative therapies and understanding regulatory requirements in Japan."

The impact from these license agreements on the projected business performance of this fiscal year (ending March 2012) will be immaterial.

About Merck Serono

Merck Serono is the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. In the United States and Canada, EMD Serono operates as a separately incorporated affiliate of Merck Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alfa), endocrine and metabolic disorders (Saizen® and Serostim®, somatropin), (Kuvan®, sapropterin dihydrochloride), (Egrifta®, tesamorelin), as well as cardiometabolic diseases (Glucophage®, metformin), (Concor®, bisoprolol), (Euthyrox®, levothyroxine). Not all products are available in

all markets.

With an annual R&D expenditure of over € 1 bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in rheumatology.

About Merck

Merck is a global pharmaceutical and chemical company with total revenues of € 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

<References>

About tumor antigen

It is known that an immune cell recognizes a certain type of protein or peptide expressed on the surface of cancer cells as an antigen, and then attacks cancer cells expressing the antigen. The protein or peptide which is recognized as an antigen is called "tumor antigen".

About multiple sclerosis

Multiple sclerosis is chronic neurological disorder accompanying diversified and severe neurological symptoms such as paralysis and numbness of limbs, gait disorder, visual disorder, dysuria. Although there are no specific factors that are known to be responsible for onset and relapse of the disease, it is thought to be one of autoimmune diseases that, because of some triggers, own body improperly recognized as foreign, is attacked by lymphocytes, which has an essential role in immune system for protection from foreign substances such as virus and bacteria. Most patients are diagnosed between the ages of 20 and 40, and women tend to suffer disproportionately from this disease compared to men. Patient number in Japan is around 12,000, but it's said that there are at least 350,000 patients in US and about 2.5 million ones all over the world.

About non-small cell lung cancer

Lung cancer is classified into two types, non-small-cell lung cancer and small-cell lung cancer. Non-small-cell lung cancer constitutes 80% of total lung cancer. In Japan, the number of deaths due to lung cancer accounts for 19.6% of total cancer death. Lung cancer is the highest frequency of cancer death in men, and is the second behind colorectal cancer in women**. Smoking is the strongest risk factor for lung cancer, and it's reported that risk of lung cancer for smokers is 4.4 times as much as that of non-smokers in men, and 2.8 times in women***.

- ** "Demographics survey" (demographics statistics in 2009) by Health, Labour and Welfare Ministry
- *** Homepage of "Center for Cancer Control and Information Services" by NATIONAL CANCER CENTER (incorporated administrative agency)