

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2014

Supplemental Information

New Drugs in Development

as of May 13, 2014

In our ongoing effort to create products that will promote the health of more people worldwide, Ono has many new drug formulations under development, including the following main drugs:

Glactiv[®] Tablet (ONO-5435 / MK-0431)

Japan: J-NDA approved / type 2 diabetes with severe renal dysfunction (12.5 mg, new formulation, co-development with Merck & Co., Inc.), J-NDA filed / combination therapy with a rapid-acting insulin secretagogue for type 2 diabetes (additional indication, co-development with Merck & Co., Inc.)

Onoact[®] Intravenous Infusion 150 mg (ONO-1101)

Japan: J-NDA filed / post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function (additional formulation)

Proemend[®] Intravenous Infusion (ONO-7847 / MK-0517) (In-licensed from Merck & Co., Inc.)

Japan: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

Rivastach[®] Patch (ONO-2540 / ENA713D)

Japan: Phase III / Alzheimer's disease (administration change) (co-development with Novartis Pharma AG)

Opalmon[®] Tablets (OP-1206 · α -CD)

Japan: J-NDA filed / thromboangitis obliterans, lumbar spinal canal stenosis (new formulation, co-development with Dainippon Sumitomo Pharma Co., Ltd.)

ONO-4538 / BMS-936558 (injection)

ONO-4538, a human anti-human PD-1 monoclonal antibody, is expected to be a potential treatment for cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.

Japan: J-NDA filed / melanoma, Phase III / renal cell cancer (global clinical trial), Phase II / non-small cell lung cancer, Phase II / esophageal cancer

Overseas: Phase III / renal cell cancer (Bristol-Myers Squibb Company, global clinical trial), Phase III / melanoma (Bristol-Myers Squibb Company), Phase II / follicular lymphoma (Bristol-Myers Squibb Company), Phase I/II / colon cancer (Bristol-Myers Squibb Company), Phase I/II / solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer) (Bristol-Myers Squibb Company)

US & Other Countries: Phase III / non-small cell lung cancer (Bristol-Myers Squibb Company), Phase II / glioblastoma (Bristol-Myers Squibb Company), Phase II / diffuse large B cell lymphoma (Bristol-Myers Squibb Company),

US: Phase I / Hepatitis C (Bristol-Myers Squibb Company), Phase I / Hepatocellular carcinoma (Bristol-Myers Squibb Company)

ONO-4164 / BMS-188667 (injection) (In-licensed from Bristol-Myers Squibb Company)

ONO-4164 is an intravenous preparation of Orencia[®] and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and overseas where it is indicated for use in patients with juvenile idiopathic arthritis.

Japan: Phase III / juvenile idiopathic arthritis (additional indication) (co-development with Bristol-Myers Squibb Company), Phase III / lupus nephritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)

Overseas: Phase III / lupus nephritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

ONO-7057 / Carfilzomib (injection)(In-licensed from Onyx Pharmaceuticals, Inc.)

ONO-7057 is a proteasome inhibitor being developed for multiple myeloma, which is a cancer of plasma cells (one of blood cells). ONO-7057 is highly expected to be a new treatment option for poor prognosis multiple myeloma.

Japan: Phase III / multiple myeloma

Overseas: Approved under Accelerated Drug Approval Program in US / multiple myeloma (launched in August 2012)

Phase III in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-2745 / CNS 7056 (injection)(In-licensed from PAION AG)

ONO-2745 is a GABA_A receptor modulator, an innovative short-acting general anaesthetic and sedative, and is under clinical development as a sedative agent during the induction and maintenance of general anesthesia. The sedative effects rapidly disappear after cessation of administration due to its metabolism by esterase enzymes, and therefore it is expected to be a drug with improved controllability and safety profile.

Japan: Phase II / III / general anesthesia,

Europe: Phase II / general anesthesia (PAION AG)

US: Phase II / procedural sedation (PAION AG)

ONO-7165 / EMD531444 (injection) (In-licensed from Merck KGaA)

ONO-7165 is a liposome vaccine being developed for non-small cell lung cancer. ONO-7165 is a cancer immunotherapy targeting the tumor antigen, MUC-1. It is thought that an immune cell recognizes MUC-1 as tumor antigen, and then attacks cancer cells expressing MUC-1.

Japan: Phase II / non-small cell lung cancer (co-development with Merck KGaA)

Overseas: Phase III / non-small cell lung cancer (Merck KGaA)

ONO-4641 (tablet)

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist, being developed for the treatment of multiple sclerosis. ONO-4641 is a low molecular weight substance that keeps lymphocytes in lymph nodes and reduces the lymphocyte count in the blood, thereby inhibiting the infiltration of lymphocytes into lesions. ONO-4641 is therefore expected to be an innovative drug for the treatment of auto-immune diseases such as multiple sclerosis, which is regarded as an intractable disease.

Japan: Phase II / multiple sclerosis (global clinical trial)

US and Europe: Phase II / multiple sclerosis (Merck KGaA, global clinical trial)

ONO-3849 / Methylnaltrexone bromide (injection)(In-licensed from Progenics Pharmaceuticals, Inc.)

ONO-3849 is a peripherally acting mu-opioid receptor antagonist, and is developed for intractable opioid induced constipation. Opioid pain medications are often used for the treatment of pain in cancer and other advanced illnesses, but cause constipation in many of these patients. ONO-3849 is expected to decrease the constipating effects of opioid analgesics in the gastrointestinal tract without affecting their ability to relieve pain.

Japan: Phase II / opioid-induced constipation

Overseas: Marketed (Salix Pharmaceuticals, Inc.)

ONO-7643 / RC-1291 (tablet)(In-licensed from Helsinn Therapeutics (US), Inc.)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

Japan: Phase II / cancer anorexia / cachexia

US & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-5163 / AMG-416 (injection) (In-licensed from Amgen Inc.)

ONO-5163 is a calcium sensing receptor agonist currently being developed for the treatment of secondary hyperparathyroidism.

Japan: Phase I / II / secondary hyperparathyroidism

US: Phase III / secondary hyperparathyroidism (Amgen Inc.)

ONO-6950 (tablet)

ONO-6950 is a leukotriene receptor antagonist, and is under clinical development for bronchial asthma. It is expected to improve symptoms associated with the disease by inhibiting airway inflammation.

Japan: Phase I / bronchial asthma

US: Phase II / bronchial asthma

ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Pharmaceuticals, Inc.)

ONO-7056 is a Ras signal inhibitor which is expected to be effective in the cancers, such as pancreatic cancer, in which high RAS genetic mutation is found.

Japan: Phase I / solid tumor

US: Phase I / pancreatic cancer (Kadmon Pharmaceuticals, Inc.)

ONO-7268MX1 / ONO-7268MX2 (injection) (In-licensed from OncoTherapy Science, Inc.)

ONO-7268MX1 and ONO-7268MX2 are peptide vaccines and are expected to have effects on cancers such as hepatocarcinoma.

Japan: Phase I / hepatocarcinoma

ONO-1162 (tablet) (In-licensed from Servier)

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

Japan: Phase II / chronic heart failure

Overseas: Marketed / stable angina, chronic heart failure (Servier)

ONO-2160/CD (tablet)

ONO-2160 is a combination product with levodopa pro-drug and carbidopa which is currently developed for Parkinson's disease.

Japan: Phase I / Parkinson's disease

ONO-4053 (tablet)

ONO-4053 is a PGD2 receptor antagonist and is under clinical development for allergic rhinitis. It is expected to improve particularly nasal congestion, one of the three major symptoms of allergic rhinitis such as nasal congestion, sneezing and nasal discharge.

Japan: Phase I / allergic rhinitis

Europe: Phase II / allergic rhinitis

ONO-2952 (tablet)

ONO-2952 is an antagonist of translocator protein (TSPO) that is involved in neurosteroid production mainly in central nervous system, and is under clinical development for irritable bowel syndrome. It is expected to improve various symptoms of the disease by blocking the mechanism eliciting abnormality of brain-gut interactions under stress.

US: Phase II / IBS

ONO-8539 (tablet)

ONO-8539 is a prostaglandin receptor (EP1) antagonist being developed for the treatment of gastroesophageal reflux disease (GERD).

Europe: Phase I /GERD

ONO-9054 (eye drop)

ONO-9054 is a prostaglandin receptor (FP/EP3) agonist being developed for glaucoma and ocular hypertension.

US: Phase II / glaucoma and ocular hypertension

ONO-4059 (capsule)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma.

Europe: Phase I / B cell lymphoma

ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

Europe: Phase I / underactive bladder

ONO-1266 (capsule)

ONO-1266 is a sphingosine-1-phosphate receptor (SIP) antagonist being developed for the treatment of portal hypertension.

US: Phase I /portal hypertension

ONO-4232 (injection)

ONO-4232 is a prostaglandin receptor (EP4) agonist being developed for the treatment of acute heart failure.

US: Phase I /acute heart failure

ONO-2370/BIA9-1067 (tablet) (In-licensed from Bial)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. Bial is currently conducting the Phase III trials overseas and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

Europe: Phase III /Parkinson's disease (Bial)