

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2016

Supplemental Information

New Drugs in Development

as of May 9, 2016

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:

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

Japan: J-NDA approved / Alzheimer's disease (additional dosing regimen) (co-development with Novartis Pharma AG)

Proemend[®] Intravenous Infusion (ONO-7847 / MK-0517)

Japan: J-NDA approved in March 2016 / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

USA & Other Countries: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication) (Merck & Co., Inc.)

ONO-7057 / Carfilzomib (injection)

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 multiple myeloma of which prognosis is considered poor.

Japan: J-NDA filed / multiple myeloma, Phase III / multiple myeloma (Additional Dosing Regimen)

Overseas: Approved in the United States / multiple myeloma (launched in August 2012), Filed in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-4164IV / BMS-188667IV (injection)

ONO-4164IV 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-4164SC / BMS-188667SC (injection)

ONO-4164SC is a subcutaneous formulation of Orencia[®] and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed.

Japan: J-NDA approved in February 2016 / Orencia[®] SC 125 mg Auto-injector 1 mL, Phase III / rheumatoid arthritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)

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

ONO-5163 / AMG-416 (injection)

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

Japan: J-NDA filed / secondary hyperparathyroidism

Overseas (USA & Europe): Filed / secondary hyperparathyroidism (Amgen Inc.)

ONO-1162 (tablet)

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 III / chronic heart failure

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

Onoact[®] Intravenous Infusion 50mg/150 mg (ONO-1101) (injection)

Japan: Phase II/III / tachyarrhythmia in low cardiac function in pediatric patients (additional indication), Phase II/III / ventricular arrhythmia (additional indication)

ONO-7643 / RC-1291 (tablet)

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
USA: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)
Europe: Filed / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

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 II / bronchial asthma
USA: Phase II / bronchial asthma

ONO-2370/Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. ONO-2370 is filed in Europe by Bial 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.

Japan: Phase II / Parkinson's disease
Europe: Filed / Parkinson's disease (Bial)

ONO-5371/ Metyrosine (capsule)

ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 was approved and launched in the United States in 1979. In Japan, the Review Committee on Unapproved and Off-Label Drugs with High Medical Needs, set up by the Ministry of Health, Labour and Welfare (MHLW) regarded metyrosine as a drug with high medical needs and MHLW publicly sought pharmaceutical companies to develop metyrosine.

Japan: Phase I/II / pheochromocytoma
USA: Marketed / pheochromocytoma (Valeant Pharmaceuticals North America LLC)

ONO-7268MX1 / ONO-7268MX2 (injection)

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

Japan: Phase I / hepatocellular carcinoma

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-4059 (capsule)

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

Japan: Phase I / B cell lymphoma
USA & Europe: Phase I / B cell lymphoma (Gilead Sciences, Inc.)

ONO-8577 (tablet)

ONO-8577 is a bladder smooth muscle relaxant being developed for the treatment of overactive bladder.

Japan: Phase I / overactive bladder

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.

USA: Phase II / Irritable bowel syndrome

ONO-9054 (eye drop)

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

USA: Phase II / glaucoma and ocular hypertension (Santen Pharmaceutical Co., Ltd.)

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 (S1P) antagonist being developed for the treatment of portal hypertension.

USA: Phase I /portal hypertension

ONO-4232 (injection)

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

USA: Phase I /acute heart failure

ONO-4474 (capsule)

ONO-4474 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of osteoarthritis.

Europe: Phase I /osteoarthritis

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.

In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan:

Launched in September 2014 / melanoma,
J-NDA approved in December 2015 / non-small cell lung cancer,
J-NDA filed / renal cell cancer,
J-NDA filed / hodgkin's lymphoma,
Phase III / head and neck cancer (global clinical trial),
Phase III / gastric cancer (global clinical trial),
Phase III / esophageal cancer (global clinical trial),
Phase III / small cell lung cancer (global clinical trial),
Phase III / urothelial cancer (global clinical trial),
Phase III / hepatocellular carcinoma (global clinical trial),
Phase III / glioblastoma (global clinical trial),
Phase II / ovarian cancer,
Phase II / solid tumor (cervical cancer, endometrial cancer, soft tissue sarcoma),
Phase II / malignant pleural mesothelioma,
Phase I/II / virus-positive/negative solid tumor (global clinical trial),
Phase I / biliary tract cancer,
Phase I / Solid tumor (combination with Urelumab)

Overseas:

USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
USA / Approved in March 2015 / squamous non-small cell lung cancer,
Europe / Approved in June 2015 / melanoma,

Europe / Approved in July 2015 / squamous non-small cell lung cancer,

USA / Approved in September 2015 / melanoma (combination with Yervoy),

USA / Approved in October 2015 / non-squamous non-small cell lung cancer,

USA / Approved in November 2015 / renal cell cancer,
Europe / Approved in April 2016 / non-squamous non-small cell lung cancer,

South Korea / Approved in April 2016 / non-small cell lung cancer,

Europe / Approved in April 2016 / renal cell cancer,

Taiwan / Approved in May 2016 / melanoma,

Taiwan / Approved in May 2016 / squamous non-small cell lung cancer,

Europe / Filed / melanoma (combination with Yervoy),
Taiwan / Filed / non-squamous non-small cell lung cancer,

USA, Europe / Filed / hodgkin's lymphoma,

Taiwan / Filed / renal cell cancer,

South Korea, Taiwan / Phase III / gastric cancer,

USA, Europe, South Korea, Taiwan / Phase III / esophageal cancer,

USA, Europe, South Korea, Taiwan / Phase III / head and neck cancer,

USA, Europe / Phase III / glioblastoma,

USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,

USA, Europe, South Korea, Taiwan / Phase III / urothelial cancer,

USA, Europe, South Korea, Taiwan / Phase III / hepatocellular carcinoma,

USA, Europe / Phase II / diffuse large B cell lymphoma,

USA, Europe / Phase II / follicular lymphoma,

USA, Europe / Phase I/II / colon cancer,

USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer),

USA, Europe, South Korea, Taiwan / Phase I/II / virus-positive/negative solid tumor,

USA, Europe / Phase I / hematological cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc),

USA, Europe / Phase I / chronic myelocytic leukemia,

USA, Europe / Phase I / hepatitis C