

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2017

Supplemental Information

New Drugs in Development

as of May 8, 2017

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:

KYPROLIS[®] for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)

Kyprolis (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: Launched in August 2016 / multiple myeloma, J-NDA filed / multiple myeloma (additional dosage and administration), Phase III / multiple myeloma (change of dosage and administration)

Overseas: Launched in August 2012 / United States / multiple myeloma, Launched in November 2015 / Europe / multiple myeloma (Amgen Inc.)

Orencia[®] IV (ONO-4164) / BMS-188667 (injection)

Orencia (ONO-4164) 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 of rheumatoid arthritis for whom other therapies have failed and with juvenile idiopathic arthritis.

Japan: J-NDA filed / juvenile idiopathic arthritis (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)

Orencia[®] SC (ONO-4164) / BMS-188667 (injection)

Orencia (ONO-4164) is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed.

Japan: Launched in May 2016 / Orencia[®] SC 125 mg Auto-injector 1 mL, Phase III / untreated rheumatoid arthritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial), Phase III / primary sjögren syndrome (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)

Overseas: Approved in September 2016 / untreated rheumatoid arthritis

PARSABIV[®] / ONO-5163 / AMG-416 / Etelcalcetide Hydrochloride (injection)

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

Japan: Launched in February 2017 / secondary hyperparathyroidism

Overseas: Approved in November 2016 / Europe / secondary hyperparathyroidism, Approved in February 2017 / United States / secondary hyperparathyroidism (Amgen Inc.)

ONO-1162 / Ivabradine (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[®] for Intravenous Infusion 50mg/150 mg (ONO-1101) (injection)

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

ONO-7643 / Anamorelin (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 III / cancer anorexia / cachexia

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

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

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 overseas 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: Approved in July 2016 / 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 / CD 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 II / B cell lymphoma (Gilead Sciences, Inc.)

ONO-4059 (tablet)

ONO-4059 is a Btk inhibitor being developed for the treatment of Sjögren syndrome.

USA: Phase II / Sjögren syndrome (Gilead Sciences, Inc.)

ONO-8577 (tablet)

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

Japan: Phase II / overactive bladder

ONO-4578 (tablet)

ONO-4578 is a prostaglandin receptor (EP4) antagonist being developed for the treatment of solid tumor.

Japan: Phase I / solid tumor

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-4474 (capsule)

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

Europe: Phase II /osteoarthritis

ONO-7475 (tablet)

ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia.

USA: Phase I / acute leukemia

ONO-7579 (tablet)

ONO-7579 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of solid tumor.

USA & Europe: Phase I / solid tumor

**Opdivo® Intravenous Infusion
(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:

Launched in September 2014 / melanoma,
J-NDA approved in December 2015 / non-small cell lung cancer,
J-NDA approved in August 2016 / renal cell carcinoma,
J-NDA approved in December 2016 / hodgkin's lymphoma,
J-NDA approved in March 2017 / head and neck cancer,
J-NDA filed / gastric cancer (global clinical trial),
Phase III / esophageal cancer (global clinical trial),
Phase III / gastro-esophageal junction cancer and 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 III / malignant pleural mesothelioma (global clinical trial),
Phase III / ovarian cancer,
Phase II / solid tumor (cervix carcinoma, uterine body cancer, soft tissue sarcoma),
Phase II / central nervous system lymphoma, primary testicular lymphoma (global clinical trial),
Phase I/II / virus positive/negative solid carcinoma (global clinical trial),
Phase I / biliary tract cancer

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 carcinoma,
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 carcinoma,
USA / Approved in May 2016 / hodgkin's lymphoma,
Europe / Approved in May 2016 / melanoma (combination with Yervoy),
Taiwan / Approved in May 2016 / melanoma,
Taiwan / Approved in May 2016 / squamous non-small cell lung cancer,
Europe / Approved in November 2016 / hodgkin's lymphoma,
USA / Approved in November 2016 / head and neck cancer,
USA / Approved in February 2017 / urothelial cancer,
Taiwan / Approved in April 2017 / renal cell carcinoma
Europe / Approved in April 2017 / head and neck cancer,
USA / Filed / colon cancer,
Europe / Filed / urothelial cancer,
Taiwan / Filed / non-squamous non-small cell lung cancer,
Taiwan / Filed / head and neck cancer,
USA, Europe / Phase III / multiple myeloma,
USA, Europe, South Korea, Taiwan / Phase III / gastric cancer,
USA, Europe, South Korea, Taiwan / Phase III / esophageal cancer,
USA, Europe, South Korea, Taiwan / Phase III / gastro-esophageal junction cancer and esophageal cancer,
South Korea / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,
South Korea, Taiwan / Phase III / urothelial cancer,
USA, Europe, South Korea, Taiwan / Phase III / hepatocellular carcinoma,
USA, Europe / Phase III / malignant pleural mesothelioma,
USA, Europe / Phase II / central nervous system lymphoma, primary testicular lymphoma,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
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 carcinoma,
USA, Europe / Phase I / hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc),
USA, Europe / Phase I / chronic myeloid leukemia,
USA, Europe / Phase I / hepatitis C
USA / Phase I / Sepsis

Urelumab (ONO-4481) / BMS-663513 (injection)

ONO-4481, a human anti-human CD-137 monoclonal antibody, is expected to be a potential treatment for cancer etc.

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: Phase I / solid tumor

ONO-4482 / BMS-986016 (injection)

ONO-4482, a human anti-human LAG-3 monoclonal antibody, is expected to be a potential treatment for cancer etc.

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: Phase I / solid tumor

ONO-4686 / BMS-986207 (injection)

ONO-4686, a human anti-human TIGIT monoclonal antibody, is expected to be a potential treatment for cancer etc.

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: Phase I/II / solid tumor

ONO-4687 / BMS-986227 (injection)

ONO-4687, a human anti-human CSF-1R monoclonal antibody, is expected to be a potential treatment for cancer etc.

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: Phase I / solid tumor and hematologic cancer

ONO-7701 / BMS-986205 (capsule)

ONO-7701, IDO1 inhibitor, is expected to be a potential treatment for cancer etc.

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: Phase I / solid tumor and hematologic cancer

ONO-4483 / BMS-986015 (injection)

ONO-4483, a human anti-human KIR monoclonal antibody, is expected to be a potential treatment for cancer etc.

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: Phase I / solid tumor