Key Product Profiles

ONCOLOGY | Sales in FY2017 | Percentage increase/ decrease from FY2016

OPDIVO

Intravenous Infusion for the Treatment of Malignant Tumors

90.1 billion yen

–13.3%

OPDIVO is an anticancer drug approved in Japan for cancer immunotherapy targeting PD-1, a world first. It is an immune checkpoint inhibitor that reactivates antitumor immune response using the body's immune system.

It was launched in Japan in September 2014 for unresectable melanoma and before the end of March 2018 received additional approval for unresectable, advanced or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy. The number of patients using OPDIVO during FY2017 totals around 17,000. Although the drug price was reduced by 50% in February 2017, FY2017 sales reached 90.1 billion yen thanks to an approximate 45% year-on-year increase in volume terms.

ONO saw increases in sales of OPDIVO in the world except Japan, South Korea and Taiwan, with its partner Bristol-Myers Squibb (U.S.A.) obtaining regulatory approval in more than 60 countries for the treatment of several types of cancer. Accordingly, royalty income from OPDIVO sales overseas totaled 39.8 billion yen.

While promoting OPDIVO's proper use and collecting information on its safety, ONO is working hard on adding indications for other cancers, extending the therapy line as well as developing combination therapies. ONO will continue working to maximize OPDIVO's value. In the drive to add more indications to OPDIVO, ONO is currently working to obtain approval for more than 20 additional indications for cancers. In FY2018, the company plans to apply for approval of partial changes for OPDIVO, including in therapy line expansion and combination therapy.

OPDIVO: Development Status (Late stage)

As of July 31, 2018

Target Disease		Development Stage		
		Japan	US&EU	South Korea & Taiwan
Melanoma	First-and later-line treatment	Approved	Approved	Approved
	Adjuvant therapy	Filing	Approved (US) / Filing (EU)	Ⅲ
Non-small cell lung cancer	Second- and later-line treatment	Approved	Approved	Approved
	First-line treatment	Ⅲ	Filing	Ⅲ
Renal cell carcinoma	Second- and later-line treatment	Approved	Approved	Approved
	First-line treatment	Filing	Approved (US) / Filing (EU)	Ⅲ
Hodgkin lymphoma		Approved	Approved	Approved
Head and neck cancer		Approved	Approved	Approved
Gastric cancer		Approved	Ⅲ	Approved
Urothelial carcinoma		Ⅲ	Approved	Approved
Hepatocellular carcinoma		Ⅲ	Approved (US) / Ⅲ (EU)	Ⅲ (KR) / Approved (TW)
Colorectal cancer		Ⅱ / Ⅲ	Approved (US) / Ⅱ / Ⅲ (EU)	-
Malignant pleural mesothelioma		Filing	Ⅲ	–
Small cell lung cancer		Ⅲ	Filing (US) / Ⅲ (EU)	Ⅲ
Gastric or esophago-gastric junction cancer		Ⅲ	Ⅲ	Ⅲ
Esophageal cancer		Ⅲ	Ⅲ	Ⅲ
Glioblastoma		Ⅲ	Ⅲ	-
Multiple myeloma		Ⅱ	Ⅲ	-
Ovarian cancer		Ⅲ	Ⅲ	-

ONCOLOGY

KYPROLIS
for Intravenous Injection for the Treatment of Malignant Tumors

5.5 billion yen
+182.4%

KYPROLIS is a highly selective inhibitor that inhibits the action of proteasome, an enzyme complex within human cells, thereby causing functional cell death of myeloma cells. In August 2016, it was launched as a drug to treat relapsed or refractory multiple myeloma. In May 2017, additional approval was obtained for 2-drug therapy in combination with dexamethasone, widening the treatment options. Multiple myeloma is a hematological malignancy caused by abnormality of plasma cells in the bone marrow. Although several regimens for multiple myeloma are currently available, the disease relapses and progresses and eventually no longer responds to therapy, also known as refractory disease. Additionally, adverse drug reactions and co-morbid conditions have been reported following long-term treatment, making continued treatment difficult.
Sales of KYRPOLIS reached 5.5 billion yen in FY2017. Amid increased competition from the fast-paced launch of new anti-multiple myeloma drugs, ONO will continue promotion of proper use and other information dissemination to expand the market share for KYPROLIS.

EMEND Capsules / PROEMEND
for Intravenous Injection for the Treatment of Chemotherapy-induced Nausea and Vomiting

9.9 billion yen
+0.7%

EMEND / PROEMEND is the first selective neurokinin (NK) 1 receptor antagonist in the world. It is effective for chemotherapy-induced nausea and vomiting. EMEND Capsules (oral) or PROEMEND (injection) are used in at least 80% of cases in which an anticancer drug with a high risk of inducing nausea and vomiting is used, and in at least 40% of cases in which an anticancer drug with a moderate risk of inducing nausea and vomiting is used. In March 2016, PROEMEND received additional approval for use in infants over six-months and in pediatric patients under 12-years of age, which enabled medical practitioners to administer the drug to pediatric patients who have common difficulty in taking capsules orally. Meanwhile, changes to standard cancer therapy have led to a reduced number of patients treated with highly emetogenic anti-cancer drugs. The sales of EMEND and PROEMEND together reached 9.9 billion yen in FY2017.
Major overseas guidelines (including MASCC/ESMO Antiemetic Guidelines, NCCN Guidelines, and ASCO Guidelines) have recommended the use of EMEND for patients using carboplatin regimen. ONO will therefore boost activities for the drug and increase its use in lung and gynecological cancers, which can be treated with it.

Key Product Profiles

NEW PRODUCTS | Sales in FY2017 | Percentage increase/ decrease from FY2016

GLACTIV Tablets

for the Treatment of Type 2 Diabetes

27.4 billion yen

–6.7%

GLACTIV, a dipeptidyl-peptidase (DPP) 4 inhibitor, is an oral drug for treatment of type 2 diabetes. It regulates blood sugar levels in type 2 diabetes patients with the mechanism of action selectively inhibiting DPP-4, an enzyme that metabolizes a gastrointestinal hormone, incretin. It thereby enhances the body's own insulin secretion ability in a glucose dependent manner and decreases glucagon release, signaling the liver to reduce its production of glucose. GLACTIV has been impacted by competitors such as combination drugs and once-weekly administered formulations but the population of potential diabetes patients is large and GLACTIV has the strength of being a product with a rich evidence base and a large amount of efficacy and safety information accumulated through its long-term use by patients in Japan. ONO will therefore carry on its effort at earning its reputation for GLACTIV Tablets being the first-choice drug in treatment of type 2 diabetes.

ORENCIA

for Subcutaneous Injection for the Treatment of Rheumatoid Arthritis

14.1 billion yen

+22.0%

ORENCIA is a subcutaneous injection for the treatment of rheumatoid arthritis. It inhibits secretion of cytokines by blocking the signal that activates T cells, resulting in the suppression of joint inflammation. ORENCIA for subcutaneous injection, evaluated in terms of both efficacy and safety, is seeing increased use. In addition, ORENCIA auto-injector, a new dosage form launched in May 2016, is now penetrating the market. It has given an additional treatment option to practitioners and is easier for patients to administer physically and functionally, giving hope that it can be of benefit to patients who have difficulty with self-injection due to problems such as joint deformity. ONO will continue directing efforts toward raising patients' quality of life.

FORXIGA Tablets

for the Treatment of Type 2 Diabetes

11.1 billion yen

+41.8%

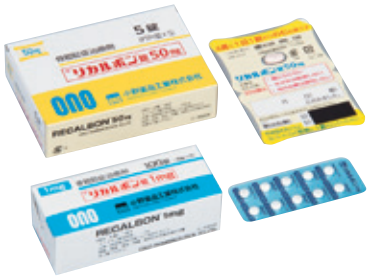
FORXIGA is an oral drug for the treatment of type 2 diabetes. This drug reduces blood sugar by excreting excess blood glucose via urine through the inhibition of SGLT2, a transporter that acts to regulate reabsorption of glucose in the kidney tubules. It improves high blood sugar after meals and fasting blood sugar levels, independently of insulin. FORXIGA, the first SGLT2 inhibitor in the world, keeps a top-class share in sales among drugs of the same mechanism of action based on the strength of ample evidence globally. We will continue taking advantage of ONO's track record in the diabetes area along with our marketing partner AstraZeneca, so as to add new prescriptions of FORXIGA.

RECALBON Tablets

for the Treatment of Osteoporosis

10.9 billion yen

–3.3%

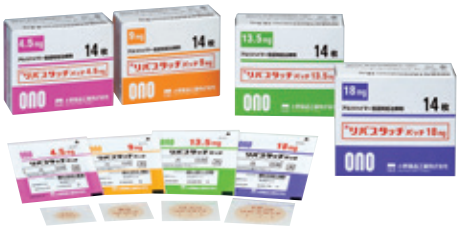


RECALBON is the first oral bisphosphonate discovered in Japan for the treatment of osteoporosis. Although the osteoporosis drug market faces intense competition due to the entrance of new drugs and the proliferation of generic bisphosphonates on the market, with 20-30% of osteoporosis patients currently receiving drug therapy, much of the market remains to be exploited, so ONO will press ahead to penetrate the market, using as a strong selling point its features—namely its powerful bone resorption inhibition—together with the fact that it allows verification against placebo of fracture prevention effectiveness in Japanese osteoporosis patients.

NEW PRODUCTS

RIVASTACH Patch
for the Treatment of Alzheimer's Disease

8.9 billion yen
+0.3%



RIVASTACH Patch is a transdermal patch for the treatment of Alzheimer's disease. It reduces the progression of deteriorating cognitive functions such as memory loss (forgetfulness) and disorientation (inability to recognize time and place) by inhibiting acetylcholinesterase and thereby increasing the amount of acetylcholine in the brain and enhancing neurotransmission. ONO will communicate the characteristics of RIVASTACH's dosage form of patch as well as its efficacy and safety to continue dissemination of information. ONO will also work on disseminating drug therapy guidance based on the Clinical Practice Guideline for Dementia.

PARSABIV Intravenous Infusion
for Dialysis for the Treatment of Secondary Hyperparathyroidism in Patients on Hemodialysis

3.4 billion yen
Launch: February 2017

PARSABIV is a drug to treat secondary hyperparathyroidism, a complication of chronic renal failure. The drug reduces the excessive secretion of the parathyroid hormone by activating the calcium-sensing receptor in the parathyroid glands and lowers the phosphorus and serum calcium levels in the blood. PARSABIV is an intravenous injection for dialysis patients to be administered through the dialysis circuit and such administration is expected to reduce the burden of oral medications in dialysis patients. Since its launch in February 2017, the number of prescriptions of PARSABIV has steadily risen. ONO will continue to disseminate information on PARSABIV's efficacy and safety to consolidate its rating.

ONOACT
for Intravenous Infusion for the Treatment of Intraoperative or Post-operative Tachyarrhythmia, or Tachyarrhythmia in Left Ventricular Dysfunction

5.6 billion yen
–1.8%

ONOACT is a short-acting β_1 blocker that selectively blocks β_1 receptors mainly found in the heart. It is for emergency treatment of intra-operative or post-operative tachyarrhythmia (atrial fibrillation, atrial flutter, sinus tachycardia), and for treatment of tachyarrhythmia in left ventricular dysfunction (atrial fibrillation, atrial flutter).

STAYBLA Tablets
for the Treatment of Overactive Bladder (OAB)

4.1 billion yen
–13.4%

STAYBLA is a selective anticholinergic antagonist binding to muscarinic acetylcholine M3 and M1 receptors. It comes in two types, regular and orodispersible (OD) tablets. It improves urge to urinate, frequent urination, and urge incontinence, the symptoms of overactive bladder, by suppressing excessive contraction of smooth muscle in the bladder.

OTHER KEY PRODUCTS (LONG-TERM LISTED PRODUCTS)

OPALMON Tablets
for the Treatment of Peripheral Circulatory Disorder

14.4 billion yen
–15.6%

OPALMON is an orally administered prostaglandin-E_1 derivative for the treatment of ischemic symptoms accompanying thromboangiitis obliterans and subjective symptoms and walking disability associated with acquired lumbar spinal canal stenosis. It improves symptoms caused by peripheral circulatory disorder such as numbness, pain or coldness of the hands or feet.

ONON Capsules / Dry Syrup
for the Treatment of Bronchial Asthma and Allergic Rhinitis

8.8 billion yen
–19.3%

Both ONON Capsules and ONON Dry Syrup are leukotriene receptor antagonists. Leukotriene is closely involved in the basic pathologies of bronchial asthma and of allergic rhinitis. The drug relieves asthma symptoms including coughing and breathlessness, and allergic rhinitis symptoms including sneezing, runny nose, and stuffy nose. ONON Dry Syrup is a formulation suitable for use with pediatric patients.