

February 26, 2019

## Launch of BRAFTOVI® Capsule 50 mg, a BRAF Inhibitor and MEKTOVI® Tablet 15 mg, a MEK Inhibitor in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “ONO”) announced today that it has launched BRAFTOVI® Capsule 50 mg (generic name: encorafenib, “BRAFTOVI”), a BRAF inhibitor and MEKTOVI® Tablet 15 mg (generic name: binimetinib, “MEKTOVI”), a MEK inhibitor, in Japan for the indication of unresectable melanoma with a BRAF mutation.

Melanoma is a form of skin cancer that develops from the pigment-producing cells (melanocytes) which are deeply related with the skin colour, and said to be the most metastatic and deadliest form of the disease. It is reported that the number of melanoma patients is about 4,000\*<sup>1</sup> with about 700 deaths\*<sup>2</sup> due to melanoma per year in Japan.

BRAFTOVI and MEKTOVI suppress the proliferation of tumors by targeting and selectively inhibiting the key enzymes of BRAF and MEK1/MEK2, respectively, which are different kinases of a family of serine/threonine kinases in the MAPK signaling pathway (RAS-RAF-MEK-ERK) associated with melanoma and various cancers. The combination therapy is expected to provide more potent anti-tumor effects by inhibiting BRAF kinase activity and MEK1/MEK2 activity simultaneously.

In May 2017, ONO executed a license agreement regarding BRAFTOVI and MEKTOVI with U.S.-based Array BioPharma Inc. (“Array”), for exclusive rights to develop and commercialize both products in Japan and South Korea. Array retains exclusive rights to BRAFTOVI and MEKTOVI in the U.S. and Canada.

\*1: CANCER STATISTICS IN JAPAN 2013, Patient Survey (Basic Disease Classification), Ministry of Health, Labour and Welfare 2011

\*2: Vital Statistics, Ministry of Health, Labour and Welfare 2012

### **Overview of BRAFTOVI® Capsule 50 mg**

Product Name	BRAFTOVI® Capsule 50 mg
Generic name	Encorafenib
Indication	Unresectable melanoma with a BRAF mutation
Dosage and administration	In combination with binimetinib, usually, for adults, administer 450 mg of encorafenib orally once a day. According to patients’ condition, the dose should be reduced.
Package	60 capsules
Approval date	January 8, 2019
NHI price listing date	February 26, 2019
NHI drug price	¥3,180.70
Launch date	February 26, 2019
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.

## Overview of MEKTOVI® Tablet 15 mg

Product Name	MEKTOVI® Tablet 15 mg
Generic name	Binimetinib
Indication	Unresectable melanoma with a BRAF mutation
Dosage and administration	In combination with encorafenib, usually, for adults, administer 45 mg of binimetinib every 12 hours as a guide orally twice a day.
Package	100 tablets
Approval date	January 8, 2019
NHI price listing date	February 26, 2019
NHI drug price	¥4,836.80
Launch date	February 26, 2019
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.

## Product photograph



**BRAFTOVI® Capsule 50 mg**



**MEKTOVI® Tablet 15 mg**

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