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Chugai Launches Rozlytrek, an Anticancer Agent for the Treatment of *NTRK* Fusion-Positive Solid Tumors

TOKYO, September 4, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today the launch of Rozlytrek® capsules 100 mg and 200 mg (generic name: entrectinib) (hereafter, Rozlytrek), an anticancer agent/tyrosine kinase inhibitor, for the treatment of *NTRK* fusion-positive advanced or recurrent solid tumors. Rozlytrek received manufacturing and marketing approval on June 18, 2019 and was listed on the National Health Insurance (NHI) reimbursement price list on September 4.

"We are very pleased that we can now provide Rozlytrek to patients as the first drug for the treatment of *NTRK* fusion-positive solid tumors in Japan," said Dr. Osamu Okuda, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "Rozlytrek is a drug that embodies advanced personalized healthcare as it has been approved to treat solid tumors with rare gene fusions regardless of their site of origin. We will continue to take every measures to provide proper information to ensure the safe use of Rozlytrek."

Rozlytrek is a drug that will realize the advance in personalized healthcare, which is one of the goals set by Chugai. After receiving *Sakigake* designation from the Ministry of Health, Labour and Welfare (MHLW) for *NTRK* fusion-positive advanced/recurrent solid tumors with extremely rare gene mutation, Chugai obtained the world's first regulatory approval for Rozlytrek in Japan on June 18, 2019. Rozlytrek is the first drug approved in Japan for the treatment of *NTRK* fusion-positive solid tumors as a tumor agnostic treatment in both adult and pediatric patients. In other countries, Rozlytrek has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) and was approved for the treatment of *NTRK* fusion-positive solid tumors on August 15, 2019. The European Medicines Agency (EMA) has designated Rozlytrek as PRIority MEdicines (PRIME).

For Biomarker testing of *NTRK* gene fusions, Chugai obtained approval of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic for Rozlytrek by the MHLW on June 26, 2019.

As a leading company in the field of oncology, Chugai will regard Rozlytrek as the drug to realize advanced personalized healthcare in oncology and contribute to patients and healthcare professionals through the promotion of its appropriate use.

[Reference information]
Media release issued by Chugai on June 18, 2019
Title: Anti-Cancer Agent Rozlytrek, Approved for the Treatment of *NTRK* Fusion Gene Positive Advanced/Recurrent Solid Tumors
https://www.chugai-pharm.co.jp/english/news/detail/20190618150000_627.html

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Media release issued by Roche on August 16, 2019

Title: FDA approves Roche's Rozlytrek (entrectinib) for people with ROS1-positive, metastatic non-small cell lung cancer and NTRK gene fusion-positive solid tumours
https://www.roche.com/media/releases/med-cor-2019-08-16.htm

Drug Information

Product name: Rozlytrek® Capsules 100 mg
Rozlytrek® Capsules 200 mg

Nonproprietary name: Entrectinib

Indications: Neurotrophic tyrosine receptor kinase (*NTRK*) fusion-positive advanced or recurrent solid tumors

Dosage and administration:

The usual adult dosage is 600 mg entrectinib administered orally once a day. Reduce the dose as necessary depending on the patient's condition.

The usual pediatric dosage is 300 mg/m^2 (body surface area) entrectinib administered orally once a day. However, the dose should not exceed 600 mg. Reduce the dose as necessary depending on the patient's condition.

Dose for pediatric patients (300 mg/m^2 administered orally once a day)

Body surface area (m^2)	Dose (once a day)
0.43-0.50	100 mg
0.51-0.80	200 mg
0.81-1.10	300 mg
1.11-1.50	400 mg
≧1.51	600 mg

Date of approval: June 18, 2019

Date of NHI reimbursement price listing: September 4, 2019

Date of launch: September 4, 2019

Shelf life: 24 months

Approval conditions:

1. A drug risk management plan is to be prepared and appropriately implemented.
2. Given that the number of patients in clinical studies in Japan was extremely limited, postmarketing drug use surveillance of all patients receiving ROZLYTREK should be conducted until data for a certain number of patients have been accumulated, in order to understand background information on patients receiving ROZLYTREK, collect

early data on the safety and efficacy of ROZLYTREK, and take necessary measures for appropriate use of ROZLYTREK.

Drug price:	Rozlytrek® Capsules 100 mg	JPY 5,214.20/Capsule
	Rozlytrek® Capsules 200 mg	JPY 9,889.90/Capsule

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