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Generic Name:

Entrectinib

Trade Name:

Rozlytrek

Company:

Genentech

Notes:

On August 15, FDA [granted](#) accelerated approval to entrectinib, a treatment for adult and adolescent patients whose cancers have the specific genetic defect neurotrophic tyrosine receptor kinase (NTRK) gene fusion and for whom there are no effective treatments.

The approval includes an indication for pediatric patients, ages 12 years and older, who have NTRK fusion-positive tumors.

Entrectinib's ability to shrink tumors was evaluated in four clinical trials studying 54 adults with NTRK fusion-positive tumors. The proportion of patients with substantial tumor shrinkage (overall response rate) was 57%, with 7.4% of patients having complete disappearance of the tumor. Among the 31 patients with tumor shrinkage, 61% had tumor shrinkage persist for 9 months or longer. The most common cancer locations were the lung, salivary gland, breast, thyroid, and colon/rectum.

Entrectinib was also approved for treatment of adults with non-small cell lung cancer whose tumors are *ROS1*-positive (mutation of the *ROS1* gene) and metastatic. Clinical studies evaluated 51 adults with *ROS1*-positive lung cancer. The overall response rate was 78%, with 5.9% of patients having complete disappearance of their cancer. Among the 40 patients with tumor shrinkage, 55% had tumor shrinkage persist for 12 months or longer.

Common adverse effects include fatigue, constipation, dysgeusia, edema, dizziness, diarrhea, and nausea. The most serious adverse effects are congestive heart failure, central nervous system effects, cognitive impairment (anxiety, depression including suicidal thinking, dizziness or loss of balance, and change in sleep pattern, including insomnia and excessive sleepiness), skeletal fractures, hepatotoxicity, hyperuricemia), QT prolongation, and vision disorders.

Health professionals should inform females of reproductive age and males with a female partner of reproductive potential to use effective contraception during treatment. Women who are pregnant or breastfeeding should not take the drug because it may cause harm to a developing fetus or newborn baby.

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