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Roche gets approval for oncology drug, Rozlytrek

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FDA Approves Genentech's Personalized Medicine for Two Different Indications in ROS1-Positive Non-Small Cell Lung Cancer and NTRK Fusion-Positive Solid Tumors

Genentech, a Roche's subsidiary announced that the US Food and Drug Administration (FDA) has approved Rozlytrek™ (entrectinib) for the treatment of adults with ROS1-positive, metastatic non-small cell lung cancer (NSCLC).

The FDA has also granted accelerated approval to Rozlytrek for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.

The accelerated approval for NTRK gene fusion-positive solid tumors is based on tumor response rate and durability of response, and continued approval may be contingent upon verification and description of clinical benefit in the confirmatory trials.