

Rozlytrek[®] (entrectinib) – Expanded indication, new formulation approval

- On October 20, 2023, the [FDA announced](#) the accelerated approval of Genentech's [Rozlytrek \(entrectinib\)](#), for the treatment of adult and pediatric patients older than 1 month of age with solid tumors that:
 - Have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion, as detected by an FDA-approved test 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.
- Rozlytrek was previously granted accelerated approval for this indication in pediatric patients 12 years of age and older.
- Rozlytrek is also approved for the treatment of adult patients with *ROS1*-positive metastatic non-small cell lung cancer (NSCLC), as detected by an FDA-approved test.
- In addition to the expanded indication, the FDA approved a new oral pellet formulation of Rozlytrek. Rozlytrek was previously available in a capsule formulation.
 - The prescribing information now includes instructions for making an oral suspension from the capsules.
- The approval of Rozlytrek for the expanded indication was based on two, open-label studies (STARTRK-NG and TAPISTRY) in 33 pediatric patients with unresectable or metastatic solid tumors with a *NTRK* gene fusion. Patients received Rozlytrek in 4-week cycles until unacceptable toxicity or disease progression. The major outcome measure was overall response rate (ORR). An additional outcome measure was duration of response (DOR).
 - The ORR was 70% (95% CI: 51,84).
 - The median DOR was 25.4 months (95% CI: 14.3, not estimable).
- Rozlytrek is administered orally (or via enteral tube) once daily until disease progression or unacceptable toxicity. The recommended pediatric dosage is based on body surface area.
 - Refer to the Rozlytrek drug label for specific dosing information for solid tumors and for dosing recommendations for NSCLC.
- Genentech's launch plans for Rozlytrek oral pellets are pending. Rozlytrek oral pellets will be available as a 50 mg pellet per packet.