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Roche announces first FDA approved tumour agnostic medicine

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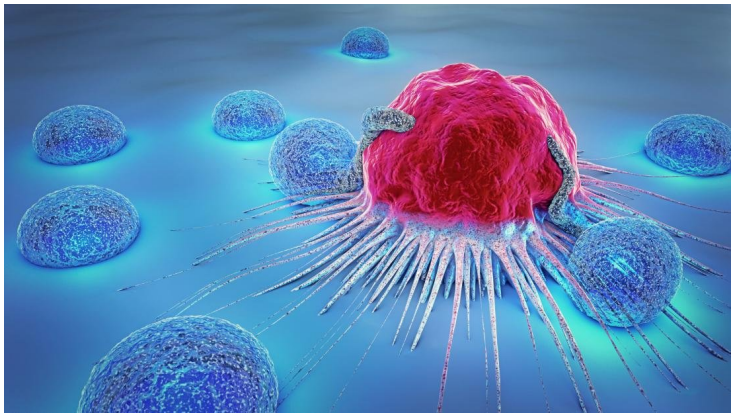
FDA approves Roche's Rozlytrek (entrectinib) for people with ROS1-positive, metastatic non-small cell lung cancer and NTRK gene fusion-positive solid tumours



Roche has 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). ROS1 is a tyrosine kinase, which plays a role in controlling how cells grow and proliferate. When a ROS1 gene fusion occurs, cancer cells grow and proliferate in an uncontrolled manner. Blocking this abnormal signalling can cause tumour cells to shrink or die.

The FDA has also granted accelerated approval to Rozlytrek for the treatment of adult and paediatric patients 12 years of age and older with solid tumours 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.

These approvals are based on results from the integrated analysis of the pivotal Phase II STARTRK-2, Phase I STARTRK-1 and Phase I ALKA-372-001 trials, and data from the Phase I/II STARTRK-NG study.

The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious or life-threatening disease or condition. The accelerated approval for NTRK gene fusion-positive solid tumors is based on tumour response rate and durability of response, and continued approval may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Biomarker testing for ROS1 in NSCLC and NTRK gene fusions across all solid tumours is the only way to identify people who are eligible for treatment with Rozlytrek. Roche is leveraging its expertise in developing personalised medicines and advanced diagnostics, in conjunction with Foundation Medicine, to help identify people with ROS1 and NTRK gene fusions. Foundation Medicine will submit FoundationOne®CDx to the FDA for approval as a companion diagnostic for Rozlytrek. An FDA-approved companion diagnostic for Rozlytrek is not available at this time.