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Japan the first to approve Roche's personalised medicine Rozlytrek

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First tumour-agnostic medicine approved in Japan for adult and paediatric patients with NTRK fusion-positive advanced recurrent solid tumours

Roche has announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved Rozlytrek® (entrectinib) for the treatment of adult and paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive, advanced recurrent solid tumours.

Rozlytrek is the first tumour-agnostic medicine to be approved in Japan that targets NTRK gene fusions, which have been identified in a range of hard-to-treat solid tumour types, including pancreatic, thyroid, salivary gland, breast, colorectal, and lung. It has been granted Sakigake designation and orphan drug designation by the MHLW.

Rozlytrek is also undergoing regulatory review in Japan for the treatment of people with ROS1 fusion-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).

"This approval of Rozlytrek represents a new chapter in personalised healthcare, applying advanced diagnostics to deliver precision medicines that target cancers based on their molecular drivers instead of their location in the body," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are proud to be at the forefront of personalised medicine with this novel treatment approach, and we look forward to working with regulatory agencies around the world to bring Rozlytrek to more patients with NTRK fusion-positive cancer, as well as to those with ROS1 fusion-positive NSCLC, as soon as possible."