Media Release

U.S. FDA approves Foundation Medicine's FoundationOne®CDx as a companion diagnostic for Roche's Rozlytrek® (entrectinib)

- **FoundationOne CDx can now be used to identify patients with ROS1 fusion-positive non-small cell lung cancer or patients with NTRK fusion-positive solid tumours for whom treatment with Rozlytrek may be appropriate**
- **This approval marks the first and only companion diagnostic indication for Rozlytrek, and another important milestone in tumour-agnostic approaches for people living with rare cancers**
- **Roche is a leader in driving personalised healthcare around the world through validated diagnostic tools, genomic insights and a continued focus on drug development**

Basel, 9 June 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the United States Food and Drug Administration (U.S. FDA) has approved Foundation Medicine's FoundationOne®CDx as a companion diagnostic (CDx) for Roche's Rozlytrek® (entrectinib). FoundationOne CDx is a comprehensive genomic profiling (CGP) pan-tumour tissue biopsy test that assesses an individual's cancer to identify the unique molecular 'fingerprint' of the tumour. It is the first and only U.S. FDA-approved CDx to identify patients with ROS1 fusion-positive non-small cell lung cancer (NSCLC), or patients with NTRK fusion-positive cancers, for whom treatment with Rozlytrek may be appropriate.

"The ability to tailor cancer therapies based on specific genomic alterations using validated comprehensive genomic profiling (CGP) has transformed the traditional 'one-size fits-all' approach to cancer," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "This approval marks a significant step forward in expanding treatment options and improving outcomes for patients, particularly those with rare tumours."

Using CGP to identify the genomic alterations that are associated with driving an individual's cancer can support physicians in making an informed treatment decision for the individual patient, potentially achieving better clinical outcomes.[1]

Rozlytrek is a targeted therapy approved to treat ROS1 fusion-positive metastatic NSCLC and a tumour-agnostic medicine for locally advanced or solid tumours that harbour NTRK fusions. ROS1 gene fusions account for 1-2% of NSCLC, the most common type of lung cancer that accounts for up to 85% of all diagnoses.[2,3] NTRK gene fusions have been identified in a range of solid tumour types, and are present in up to 90% of some rare cancer types and less than 1% of other more common cancers, including lung and colorectal.[4]

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The approval is based on data from the phase I ALKA-372-001 (EudraCT 2012-000148-88), phase I STARTRK-1 (NCT02097810) and phase II STARKTRK-2 (NCT02568267) trials. As a condition of this approval, Foundation Medicine will conduct a post-approval study powered by the Flatiron Health-Foundation Medicine's Clinico-Genomic Database (CGDB) to further demonstrate FoundationOne CDx's ability to identify patients with ROS1 fusion-mutated NSCLC for whom treatment with Rozlytrek may be appropriate. The CGDB is a de-identified, HIPAA-compliant database that links outcomes data from Flatiron's network of oncology clinics and genomic data from Foundation Medicine's CGP assays. The database currently contains more than 100,000 linked genomic profiles , and is continually growing.

By combining tumour-agnostic drug development with data collection, high-quality diagnostics and the implementation of CGP, Roche is leading the realisation of personalised healthcare around the world, enabling physicians to develop tailored treatment strategies for each individual, and enable smarter, more efficient research and development to ensure no person is left behind.

About FoundationOne®CDx

FoundationOne CDx is a next-generation sequencing-based in vitro diagnostic assay for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures, including microsatellite instability and tumour mutational burden, using DNA isolated from formalin-fixed paraffin embedded tumour tissue specimens. FoundationOne CDx is for prescription-use only and is intended as a companion diagnostic (CDx) to identify people who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumour mutation profiling to be used by qualified healthcare professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy.

FoundationOne CDx was approved by the United States Food and Drug Administration in November 2017 and is currently approved as a CDx for 25 CDx indications, and three group claims across 30 targeted therapies. For a full list of targeted therapies for which FoundationOne CDx is indicated as a CDx, please visit http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx.

About Rozlytrek® (entrectinib)

Rozlytrek is a tumour-agnostic once-daily oral medicine for the treatment of locally advanced or metastatic solid tumours that harbour NTRK1/2/3 or ROS1 gene fusions. It is a selective tyrosine kinase inhibitor designed to inhibit the kinase activity of the TRKA/B/C and ROS1 proteins, whose activating fusions drive proliferation in certain types of cancer. Rozlytrek can block NTRK and ROS1 kinase activity and may result in the death of cancer cells with NTRK or ROS1 gene fusions.

Rozlytrek is approved for the treatment of NTRK fusion-positive solid tumours and ROS1 fusion-positive non-small cell lung cancer by health authorities in more than 60 countries, including by the United States Food and Drug Administration (U.S. FDA), Japan's Ministry of Health, Labour and Welfare (MHLW) and the European Medicines Agency (EMA). Prior to approval, Rozlytrek was granted Breakthrough Therapy Designation by the U.S. FDA, Sakigake designation for accelerated review by Japan's MHLW, and Priority Medicines designation by the EMA.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

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