Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Roche's Tecentriq plus Avastin is the first treatment combination to reduce the risk of cancer returning in people with certain types of early-stage liver cancer in a Phase III trial

- **Pivotal Phase III IMbrave050 study investigating Tecentriq plus Avastin in people with early-stage hepatocellular carcinoma (HCC) at high risk of recurrence following surgery met primary endpoint of recurrence-free survival**
- **New adjuvant treatments are urgently needed as an estimated 70-80% of people with early-stage HCC experience disease recurrence following surgery[1]**
- **Data will be discussed with health authorities globally, including the US Food and Drug Administration and the European Medicines Agency to inform the next regulatory steps, and presented at an upcoming medical meeting**

Basel, 19 January 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMbrave050 study met its primary endpoint of recurrence-free survival (RFS) at the prespecified interim analysis. The study is evaluating Tecentriq® (atezolizumab) in combination with Avastin® (bevacizumab) as adjuvant treatment following surgery for people with early-stage hepatocellular carcinoma (HCC) at high risk of disease recurrence. The Tecentriq combination showed a statistically significant improvement in RFS in the intention-to-treat population of HCC patients who have an increased risk of recurrence following resection or ablation with curative intent, compared with active surveillance.

Overall survival data were immature at the time of interim analysis and follow-up will continue to the next analysis. Safety for Tecentriq and Avastin was consistent with the known safety profile of each therapeutic agent and with the underlying disease. Results from the IMbrave050 study will be discussed with health authorities, including the US Food and Drug Administration and the European Medicines Agency, and presented at an upcoming medical meeting.

"Today, more than 70% of people with early-stage HCC may have their cancer return after surgery, which is associated with poorer prognosis and shorter survival. IMbrave050 is the first Phase III study to show that a cancer immunotherapy combination reduced the risk of disease returning in people with this type of HCC," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "We are excited by the clinical benefit that this adjuvant Tecentriq combination may bring to people with early liver cancer and look forward to seeing more mature data to further confirm the benefit."

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

With liver cancer incidence increasing and mortality rates rising globally, effective treatments are urgently required.[1-4] Roche is working in partnership with the community and leveraging its diagnostic and pharmaceutical expertise to develop solutions for patients that address unmet needs at each stage of liver cancer. IMbrave050 is part of Roche's overall commitment to drive fundamental treatment change and improve outcomes for people living with liver cancer. In unresectable HCC (uHCC), for example, Tecentriq plus Avastin was the first treatment in over a decade to significantly improve overall survival over the existing standard of care, based on data from the IMbrave150 study. The Tecentriq combination quickly became a standard of care in uHCC and is clearly defined as a preferred front-line treatment in multiple international clinical guidelines.

Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across different lung, genitourinary, skin, breast, gastrointestinal, gynaecological, and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines, as well as studies in metastatic, adjuvant and neoadjuvant settings across various tumour types.

About the IMbrave050 study

IMbrave050 is a Phase III global, multicentre, open-label, randomised study evaluating the efficacy and safety of adjuvant Tecentriq plus Avastin, compared with active surveillance, in people with HCC at high risk of recurrence (determined by the size and number of cancerous lesions and the histopathology results, if available) after surgical resection or ablation with curative intent.

The study randomised 662 people with a ratio of 1:1 to receive either Tecentriq (1,200 mg every three weeks) plus Avastin (15 mg/kg every three weeks) for a maximum of 12 months, or no intervention with active surveillance. The primary endpoint is independent review facility-assessed RFS. Key secondary endpoints include overall survival, RFS as determined by the investigator and RFS in patients with PD-L1-positive disease.

About hepatocellular carcinoma

Liver cancer is the third leading cause of cancer death and one of the few cancers where mortality is rising.[3,4] More than 900,000 people are diagnosed with the disease globally each year, which translates to one person diagnosed every 90 seconds.[3] Nine out of ten cases of HCC are caused by chronic liver disease, which includes chronic hepatitis B and C infection, non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH), alcohol-related liver disease (ALD) and cirrhosis resulting from these conditions.[5]

If diagnosed in the early stage, surgery may be prescribed to remove the primary tumour, however an estimated 70-80% of people with early-stage HCC experience disease recurrence

following surgery.[1] Early recurrence is associated with poorer prognosis and shorter survival.[1,2] Tumour size, number of tumours, and portal vein invasion are associated with an increased risk of recurrence.[2]

About Tecentriq

Tecentriq is a cancer immunotherapy approved for some of the most aggressive and difficult-to-treat forms of cancer. Tecentriq was the first cancer immunotherapy approved for the treatment of a certain type of early-stage non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) and HCC. Tecentriq is also approved in countries around the world, either alone or in combination with targeted therapies and/or chemotherapies, for various forms of metastatic NSCLC, certain types of metastatic urothelial cancer, PD-L1-positive metastatic triple-negative breast cancer and BRAF V600 mutation-positive advanced melanoma.

Tecentriq is a monoclonal antibody designed to bind with a protein called programmed death ligand-1 (PD-L1), which is expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the activation of T-cells. Tecentriq is a cancer immunotherapy that has the potential to be used as a foundational combination partner with other immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers. In addition to intravenous infusion, the formulation of Tecentriq is also being investigated as a subcutaneous injection to help address the growing burden of cancer treatment for patients and healthcare systems.

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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Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Karsten Kleine
Phone: +41 79 461 86 83

Nina Mählitz
Phone: +41 79 327 54 74

Dr. Barbara von Schnurbein
Phone: +41 79 699 97 44

Sileia Urech
Phone: +41 79 935 81 48

Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com