Media & Investor Release

CHMP recommends EU approval of Roche's Tecentriq as adjuvant treatment for a subset of people with early-stage non-small cell lung cancer

- **In the Phase III IMpower010 trial, adjuvant Tecentriq reduced the risk of disease recurrence or death by 57% in people with PD-L1 high resectable Stage II-III NSCLC compared with best supportive care**
- **More than half of people with early-stage NSCLC experience disease recurrence following surgery,[1] and most of these recurrent tumours are metastatic, making them incurable[2-7]**
- **If approved, Tecentriq will be the first and only cancer immunotherapy available for certain people with early-stage NSCLC in Europe**

Basel, 22 April 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Tecentriq® (atezolizumab) as an adjuvant treatment, following complete resection and platinum-based chemotherapy, for adults with non-small cell lung cancer (NSCLC) with a high risk of recurrence whose tumours express PD-L1≥50% and who do not have EGFR mutant or ALK-positive NSCLC. A final decision regarding the approval of Tecentriq in this setting is expected from the European Commission in the near future.

"The goal of treating early-stage cancers is to provide the best chance for a cure," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's announcement brings hope that, after a decade of limited treatment advances, many people in Europe with early non-small cell lung cancer will soon have a new treatment option to reduce the risk of their disease returning."

"For approximately half of all people diagnosed with early-stage lung cancer, their disease will return at some point after surgery, and in some cases they will then be living with incurable metastatic cancer," said Anne-Marie Baird, President of Lung Cancer Europe (LuCE). "Given what we are now seeing in the early-stage space, it is vital that biomarker testing is not only confined to Stage IV disease. Testing for biomarkers at diagnosis will help to identify people who may benefit from new adjuvant treatments to help reduce disease recurrence."

The recommendation from the CHMP is based on results from the DFS interim analysis of the Phase III IMpower010 study. The results showed treatment with Tecentriq, following complete resection and platinum-based chemotherapy, reduced the risk of disease recurrence or death

(DFS) by 57% (unstratified hazard ratio [HR]=0.43, 95% CI:0.26-0.71) in people with Stage II-IIIA NSCLC (UICC/AJCC 7th edition) whose tumours express PD-L1≥50% and who do not have EGFR mutant or ALK-positive NSCLC, compared with best supportive care (BSC).[8] A DFS benefit was consistently seen across most subgroups including histology or stage of disease with adjuvant Tecentriq, compared with BSC. Overall survival (OS) data for patients with PD-L1 high resectable Stage II-IIIA NSCLC, and who do not have EGFR mutant or ALK-positive disease are immature and were not formally tested at the DFS interim analysis, however, a trend towards OS improvement with Tecentriq was seen, with a HR of 0.36 (95% CI: 0.17-0.75). Follow-up will continue with planned analyses of more mature OS data later this year. Safety data for Tecentriq were consistent with its known safety profile and no new safety signals were identified.[8]

If approved, Tecentriq will be the first cancer immunotherapy available in Europe as an adjuvant treatment, following complete resection and platinum-based chemotherapy, for adults with a high risk of recurrence whose tumours express PD-L1≥50% and who do not have EGFR mutant or ALK-positive NSCLC.

To date, Tecentriq has been approved in 14 countries, including the US and China, as an adjuvant treatment, following complete resection and chemotherapy, for adults with Stage II-IIIA (UICC/AJCC 7th edition) NSCLC whose tumours express PD-L1≥1%. In three countries, including Canada and the UK, Tecentriq has been approved as adjuvant treatment following complete resection and chemotherapy for adult patients with Stage II to IIIA (UICC/AJCC 7th edition) NSCLC whose tumours have PD-L1 expression on ≥50% of tumour cells.

Tecentriq has shown clinically meaningful benefit in various types of lung cancer, with six currently approved indications in countries around the world. It was the first approved cancer immunotherapy for the first-line treatment of adults with extensive-stage small cell lung cancer (SCLC) in combination with carboplatin and etoposide (chemotherapy). Tecentriq also has four approved indications in NSCLC as either a single agent or in combination with targeted therapies and/or chemotherapies. Tecentriq is available in three dosing options, providing the flexibility to choose administration every two, three or four weeks.

Roche has an extensive development programme for Tecentriq including multiple ongoing and planned Phase III studies across 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 IMpower010 study

IMpower010 is a Phase III, global, multicentre, open-label, randomised study evaluating the efficacy and safety of Tecentriq compared with BSC, in participants with Stage IB-IIIA NSCLC

(UICC/AJCC 7th edition), following surgical resection and up to 4 cycles of adjuvant cisplatin-based chemotherapy. The study randomised 1,005 people with a ratio of 1:1 to receive either Tecentriq (up to 16 cycles) or BSC. The primary endpoint is investigator-determined DFS in the PD-L1-positive Stage II-IIIA, all randomised Stage II-IIIA and intention-to-treat (ITT) Stage IB-IIIA populations. Key secondary endpoints include overall survival in the overall study population, ITT Stage IB-IIIA NSCLC.

About lung cancer

Lung cancer is one of the leading causes of cancer death globally.[9] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[9] Lung cancer can be broadly divided into two major types: NSCLC and SCLC. NSCLC is the most prevalent type, accounting for around 85% of all cases.[10] Approximately 50% of patients with NSCLC are diagnosed with early-stage (Stages I and II) or locally advanced (Stage III) disease.[10] Today, about half of all people with early lung cancer still experience a cancer recurrence following surgery.[1] Treating lung cancer early, before it has spread, may help prevent the disease from returning and provide people with the best opportunity for a cure.

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 hepatocellular carcinoma (HCC). Tecentriq is also approved in the EU and 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 subcutaneous injection to help address the growing burden of cancer treatment for patients and healthcare systems.

About Roche in lung cancer

Lung cancer is a major area of focus and investment for Roche, and we are committed to developing new approaches, medicines and tests that can help people with this deadly

disease. Our goal is to provide an effective treatment option for every person diagnosed with lung cancer. We currently have six approved medicines to treat certain kinds of lung cancer and more than ten medicines being developed to target the most common genetic drivers of lung cancer or to boost the immune system to combat the disease.

About Roche in cancer immunotherapy

Roche's rigorous pursuit of groundbreaking science has contributed to major therapeutic and diagnostic advances in oncology over the last 50 years, and today, realising the full potential of cancer immunotherapy is a major area of focus. With over 20 molecules in development, Roche is investigating the potential benefits of immunotherapy alone, and in combination with chemotherapy, targeted therapies or other immunotherapies with the goal of providing each person with a treatment tailored to harness their own unique immune system to attack their cancer. Our scientific expertise, coupled with innovative pipeline and extensive partnerships, gives us the confidence to continue pursuing the vision of finding a cure for cancer by ensuring the right treatment for the right patient at the right time.

In addition to Roche's approved PD-L1 checkpoint inhibitor, Tecentriq® (atezolizumab), Roche's broad cancer immunotherapy pipeline includes other checkpoint inhibitors, such as tiragolumab, a novel cancer immunotherapy designed to bind to TIGIT, individualised neoantigen therapies and T-cell bispecific antibodies.

To learn more about Roche's scientific-led approach to cancer immunotherapy, please follow this link:
http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm

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.

All trademarks used or mentioned in this release are protected by law.

References

[1] Yano T, et al. Therapeutic strategy for postoperative recurrence in patients with non-small cell lung cancer. World J Clin Oncol. 2014;5(5):1048-1054.
[2] Martin J, et al. Long-Term Results of Combined-Modality Therapy in Resectable Non-Small-Cell Lung Cancer. Journal of Clinical Oncology.2002;20(8):1989-95.
[3] Sugimura H, et al. Survival After Recurrent Nonsmall-Cell Lung Cancer After Complete Pulmonary Resection. Ann Thorac Surg. 2007;83:409-18.
[4] Shimizu R, et al. Clinicopathological Factors Related to Recurrence Patterns of Resected Non-Small Cell Lung Cancer. Journal of Clinical Medicine. 2020;9(2473):doi:10.3390/jcm9082473.
[5] Taylor MD, et al. Tumor Recurrence After Complete Resection for Non-Small Cell Lung Cancer. Ann Thorac Surg. 2012;93:1813-21.
[6] Consonni D, et al. Lung Cancer Prognosis Before and After Recurrence in a Population-Based Setting. JNCI J Natl Cancer Inst. 2015;107(6):doi:10.1093/jnci/djv059.
[7] Chouaid C, et al. Adjuvant treatment patterns and outcomes in patients with Stage IB-IIIA non-small cell lung cancer in France, Germany and the United Kingdom based on the LuCaBIS burden of illness study. Lung Cancer.2018;124:310-16.
[8] Felip E, et al. Atezolizumab vs best supportive care in Stage II-IIIA NSCLC with high PD-L1 expression: sub-analysis from the pivotal Phase III IMpower010 study. Presented at European Lung Cancer Congress (ELCC) 2022.
[9] World Health Organization: GLOBOCAN 2020 – Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. [Internet; cited April 2021] Available from: https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf.
[10] American Cancer Society: What Is Lung Cancer? [Internet; cited April 2021]: Available from: https://www.cancer.org/cancer/lung-cancer/about/what-is.html.

Roche Group Media Relations

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

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Sileia Urech
Phone: +41 79 935 81 48

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

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

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

Investor Relations North America

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