FDA grants priority review to Roche’s Tecentriq in combination with chemotherapy for the initial treatment of extensive-stage small cell lung cancer

Basel, 05 December – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has accepted the company’s supplemental Biologics License Application (sBLA) and granted Priority Review for Tecentriq® (atezolizumab), in combination with carboplatin and etoposide (chemotherapy), for the initial (first-line) treatment of people with extensive-stage small cell lung cancer (ES - SCLC). The FDA is expected to make a decision on approval by 18 March 2019. A Priority Review designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in the treatment, prevention or diagnosis of a serious disease.

“It’s been more than 20 years since there has been a new initial treatment option for extensive-stage small cell lung cancer that delivers a clinically meaningful survival benefit,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “We are working closely with the FDA to bring this Tecentriq-based regimen to people with this difficult-to-treat type of lung cancer as soon as possible.”

This sBLA is based on results from the Phase III IMpower133 study, which met its co-primary endpoints of overall survival (OS) and progression-free survival (PFS) in the initial treatment of people with ES-SCLC. The safety profile of the combination was consistent with the safety profiles of the individual medicines, and no new safety signals were identified.

Tecentriq is currently approved by the FDA to treat people with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumour has ALK or EGFR gene abnormalities.

About the IMpower133 study
IMpower133 is a Phase III, multicentre, double-blinded, randomised placebo-controlled study evaluating the efficacy and safety of Tecentriq in combination with carboplatin and etoposide versus chemotherapy (carboplatin plus etoposide) alone in chemotherapy-naïve people with ES-SCLC. The study enrolled 403 people who were randomised equally (1:1) to receive:

- Tecentriq in combination with carboplatin and etoposide (Arm A), or
- Placebo in combination with carboplatin and etoposide (Arm B, control arm)

During the treatment-induction phase, people received treatment on 21-day cycles for four cycles, followed by maintenance with Tecentriq or placebo until progressive disease (PD) as assessed by the investigator using Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST v1.1). Treatment could be continued until persistent radiographic PD or symptomatic deterioration was observed.
The co-primary endpoints were:

- PFS as determined by the investigator using RECIST v1.1 in the intention-to-treat (ITT) population
- OS in the ITT population

IMpower133 met its OS and PFS co-primary endpoints as per the study protocol. The analysis showed that Tecentriq and chemotherapy helped people live significantly longer, compared with chemotherapy alone (OS=12.3 versus 10.3 months; hazard ratio [HR]=0.70; 95% CI: 0.54–0.91; p=0.0069) in the ITT population. The 1-year OS rate for people who received the Tecentriq-based combination was 51.7%, compared with 38.2% for people who received chemotherapy alone. The Tecentriq-based combination also significantly reduced the risk of disease worsening or death (PFS) compared with chemotherapy alone (PFS=5.2 versus 4.3 months; HR=0.77; 95% CI: 0.62–0.96; p=0.017). The 1-year PFS rate for people who received the Tecentriq-based combination was 12.6%, compared with 5.4% for people who received chemotherapy alone. Safety for the Tecentriq and chemotherapy combination appeared to be consistent with the known safety profile of the individual medicines, and no new safety signals were identified with the combination.

Grade 3–4 treatment-related adverse events (AEs) were reported in 56.6% of people receiving Tecentriq plus chemotherapy, compared with 56.1% of people receiving chemotherapy alone.

**About SCLC**

Lung cancer is the leading cause of cancer death globally. Each year 1.76 million people die as a result of the disease; this translates into more than 4,800 deaths worldwide every day. Lung cancer can be broadly divided into two major types: non-small cell lung cancer (NSCLC) and SCLC, with SCLC accounting for approximately 15% of all lung cancer cases. Survival rates for people with SCLC vary depending on the stage (extent) of the cancer at the time of diagnosis. The five-year relative survival rate for people with stage I SCLC is approximately 31%; however, at stage IV, the five-year relative survival rate declines to approximately 2%.

**About Tecentriq**

Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1 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 has the potential to be used as a foundational combination partner with cancer immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers.

Currently, Roche has nine Phase III lung cancer studies underway, evaluating Tecentriq alone or in combination with other medicines.

Tecentriq is already approved in the European Union, United States and more than 80 countries for people with previously treated metastatic NSCLC and for certain types of untreated or previously treated metastatic urothelial carcinoma (mUC).
About Roche in cancer immunotherapy
For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we’re investing more than ever in our effort to bring innovative treatment options that help a person’s own immune system fight cancer.

By applying our seminal research in immune tumour profiling within the framework of the Roche-devised cancer immunity cycle, we are accelerating and expanding the transformative benefits with Tecentriq to a greater number of people living with cancer. Our cancer immunotherapy development programme takes a comprehensive approach in pursuing the goal of restoring cancer immunity to improve outcomes for patients.

To learn more about the Roche approach to cancer immunotherapy please follow this link: [http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm](http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm)

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the tenth consecutive year, Roche has been recognised as the most sustainable company in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 billion. 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](http://www.roche.com).

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