

## **Roche's TECENTRIQ in combination with chemotherapy helped people with previously-untreated extensive-stage small cell lung cancer live significantly longer compared to chemotherapy**

- **IMpower133 is the first Phase III study with an immunotherapy-based combination to show improvement in overall survival and progression-free survival in the initial treatment of extensive-stage small cell lung cancer (ES-SCLC)**
- **There has been limited treatment progress for people with ES-SCLC in the past 20 years**
- **Data will be submitted to health authorities globally, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA)**

Basel, 25 June 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpower133 study met its co-primary endpoints of overall survival (OS) and progression-free survival (PFS) at its first interim analysis. The study demonstrated that initial (first-line) treatment with the combination of TECENTRIQ® (atezolizumab) plus chemotherapy (carboplatin and etoposide) helped people with extensive-stage small cell lung cancer (ES-SCLC) live significantly longer compared to chemotherapy alone. The TECENTRIQ-based combination also reduced the risk of disease worsening or death (PFS) compared to chemotherapy alone. Safety for the TECENTRIQ and chemotherapy combination appeared consistent with the known safety profile of the individual medicines, and no new safety signals were identified with the combination. These data will be presented at an upcoming medical meeting.

“These are the first positive Phase III survival results for any immunotherapy-based combination in the initial treatment of extensive-stage small cell lung cancer, a particularly difficult-to-treat type of disease,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “The clinically meaningful results from the IMpower133 study add to the growing body of evidence demonstrating that TECENTRIQ-based combinations may be an effective treatment for different types of advanced lung cancer. We look forward to working with health authorities globally to bring this potential treatment option to people with this type of disease as soon as possible.”

This is the fourth positive Phase III lung cancer study evaluating a TECENTRIQ-based combination to read out this year and the fifth positive study overall. Currently, Roche has eight Phase III lung cancer studies underway evaluating TECENTRIQ alone or in combination with other medicines across different types of lung cancer.

### **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.

### **About SCLC**

Lung cancer is the leading cause of cancer death globally.<sup>[1]</sup> Each year 1.59 million people die as a result of the disease; this translates into more than 4,350 deaths worldwide every day.<sup>[1]</sup> 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.<sup>[2]</sup> Survival rates for people with SCLC vary depending on the stage (extent) of the cancer at the time of diagnosis.<sup>[3]</sup> 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%.<sup>[4]</sup>

### **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 eight 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 70 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row 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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### **References**

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- [2] Alvarado-Luna and Morales-Espinosa. Transl Lung Cancer Res 2016.
- [3] American Cancer Society; Key Statistics for Small Cell Lung Cancer [Internet]: <https://www.cancer.org/cancer/small-cell-lung-cancer/about/key-statistics.html>. Accessed June 2018.
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## **Roche Investor Relations**

Dr. Karl Mahler  
Phone: +41 61 68-78503  
e-mail: [karl.mahler@roche.com](mailto:karl.mahler@roche.com)

Dr. Sabine Borngräber  
Phone: +41 61 68-88027  
e-mail: [sabine.borngraeber@roche.com](mailto:sabine.borngraeber@roche.com)

Dr. Bruno Eschli  
Phone: +41 61 68-75284  
e-mail: [bruno.eschli@roche.com](mailto:bruno.eschli@roche.com)

Dr. Susann Machado  
Phone: +41 61-68-75619  
e-mail: [susann.machado@roche.com](mailto:susann.machado@roche.com)

Dr. Birgit Masjost  
Phone: +41 61 68-84814  
e-mail: [birgit.masjost@roche.com](mailto:birgit.masjost@roche.com)

## **Investor Relations North America**

Loren Kalm  
Phone: +1 650 225 3217  
e-mail: [kalm.loren@gene.com](mailto:kalm.loren@gene.com)