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Phase III IMpower131 study showed Roche's TECENTRIQ (atezolizumab) plus chemotherapy (carboplatin and Abraxane) reduced the risk of disease worsening or death in the initial treatment of people with a type of advanced squamous lung cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpower131 study met its co-primary endpoint of progression-free survival (PFS) and demonstrated that the combination of TECENTRIQ® (atezolizumab) plus chemotherapy (carboplatin and Abraxane® [albumin-bound paclitaxel; nab-paclitaxel]) reduced the risk of disease worsening or death (progression-free survival; PFS) compared with chemotherapy alone in the initial (first-line) treatment of people with advanced squamous non-small cell lung cancer (NSCLC). 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. At this interim analysis a statistically significant overall survival (OS) benefit was not observed and the study will continue as planned. These data will be presented at an upcoming oncology congress.

“Squamous non-small cell lung cancer is difficult to treat and there have been limited new treatment options over the last few decades,” said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. “We will share the IMpower131 results with global health authorities and we look forward to seeing more mature overall survival data.”

As per the statistical analysis plan in IMpower131, Arm B (TECENTRIQ plus carboplatin and nab-paclitaxel) must demonstrate a statistically significant OS result vs. Arm C (carboplatin and nab-paclitaxel), before an analysis between Arm A (TECENTRIQ plus carboplatin and paclitaxel) and Arm C can be made for PFS and OS.

Currently, Roche has eight Phase III lung cancer studies underway evaluating TECENTRIQ alone or in combination with other medicines and five are expected to report this year.

About the IMpower131 study

IMpower131 is a Phase III, open-label, multicentre, randomised study evaluating the efficacy and safety of TECENTRIQ in combination with carboplatin and nab-paclitaxel or TECENTRIQ in combination with carboplatin and paclitaxel versus chemotherapy (carboplatin and nab-paclitaxel) alone in people with stage IV squamous NSCLC who have not been previously treated with chemotherapy. The study enrolled 1,021 people who were randomised equally (1:1:1) to receive:

- TECENTRIQ plus carboplatin and paclitaxel (Arm A), or
- TECENTRIQ plus carboplatin and nab-paclitaxel (Arm B), or
- Carboplatin and nab-paclitaxel (Arm C, control arm)

During the treatment-induction phase, people in Arm A received four or six cycles of TECENTRIQ plus carboplatin and paclitaxel, given on day one of each 21-day cycle. This was followed by maintenance therapy with TECENTRIQ every three weeks until progression of the cancer, or for as long as clinical benefit was observed.

During the treatment-induction phase, people in Arm B received four or six cycles of TECENTRIQ, carboplatin and nab-paclitaxel. TECENTRIQ and carboplatin were administered on day one of each 21-day cycle. Nab-paclitaxel was administered on days one, eight and 15 of each 21-day cycle. This was followed by maintenance therapy with TECENTRIQ every three weeks until progression of the cancer, or for as long as clinical benefit was observed.

During the treatment-induction phase, people in Arm C received four or six cycles of carboplatin and nab-paclitaxel. Carboplatin was administered on day one of each 21-day cycle, and nab-paclitaxel was administered on days one, eight and 15 of each 21-day cycle. In the maintenance phase, participants received best supportive care.

The co-primary endpoints were:

- PFS as determined by the investigator using RECIST v1.1 in the intention-to-treat (ITT) population (Arm B vs. Arm C)
- Overall survival (OS) in the ITT population (Arm B vs. Arm C)

IMpower131 met its PFS co-primary endpoint per study protocol. This analysis of IMpower131 evaluated Arm B vs. Arm C.

About NSCLC

Lung cancer is the leading cause of cancer death globally.¹ Each year 1.59 million people die as a result of the disease; this translates into more than 4,350 deaths worldwide every day.² Lung cancer can be broadly divided into two major types: NSCLC and small cell lung cancer. NSCLC is the most prevalent type, accounting for around 85% of all cases.² NSCLC comprises non-squamous and squamous-cell lung cancer, the squamous form of which is characterised by flat cells covering the airway surface when viewed under a microscope. The squamous form tends to grow near the centre of the lung, and accounts for approximately 25-30% of all NSCLC cases.³

About TECENTRIQ (atezolizumab)

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 60 countries for people with previously treated metastatic NSCLC and for people with locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin chemotherapy, or who have had disease progression during or following platinum-containing therapy.

Abraxane is a registered trademark of Abraxis Bioscience, LLC, a wholly owned subsidiary of Celgene Corporation.

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

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.

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- ² Barzi A, Pennell NA. Targeting angiogenesis in non-small cell lung cancer: agents in practice and clinical development. *European J Clin Med Oncol* 2010; 2(1):31–42.
- ³ American Cancer Society; last accessed February 2018: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html>