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Phase III IMpower130 study showed Roche's Tecentriq (atezolizumab) plus chemotherapy (carboplatin and Abraxane) helped people with metastatic non-squamous NSCLC live significantly longer compared to chemotherapy alone

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpower130 study met its co-primary endpoints of overall survival (OS) and progression-free survival (PFS). The combination of Tecentriq® (atezolizumab) plus chemotherapy (carboplatin and Abraxane® [albumin-bound paclitaxel; nab-paclitaxel]) helped people live significantly longer compared to chemotherapy alone in the initial (first-line) treatment of advanced non-squamous non-small cell lung cancer (NSCLC). In addition, the Tecentriq combination reduced the risk of disease worsening or death (progression-free survival; PFS) compared with 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 oncology congress.

"The results of the IMpower130 study add to the growing evidence showing the clinical benefit of Tecentriq-based combinations in the treatment of advanced non-squamous non-small cell lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We will share these results with global health authorities with the goal of bringing this potential treatment option to people with this disease."

Currently, Roche has eight Phase III lung cancer studies underway evaluating Tecentriq alone or in combination with other medicines. This is the third positive Phase III study evaluating Tecentriq alone or in combination to demonstrate an OS benefit for people with NSCLC.

About the IMpower130 study

IMpower130 is a Phase III, multicentre, open-label, randomised study evaluating the efficacy and safety of Tecentriq in combination with carboplatin and *nab*-paclitaxel versus chemotherapy (carboplatin and *nab*-paclitaxel) alone for chemotherapy-naïve patients with stage IV non-squamous NSCLC.

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The study enrolled 724 people who were randomised (2:1) to receive:

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

During the treatment-induction phase, people in Arm A received Tecentriq and carboplatin on day 1 of each 21-day cycle, and *nab*-paclitaxel on days 1, 8 and 15 of each 21-day cycle for 4 or 6 cycles or until loss of clinical benefit, whichever occurs first. People received Tecentriq during the maintenance treatment phase until loss of clinical benefit was observed.

During the treatment-induction phase, people in Arm B received carboplatin on day 1 and *nab*-paclitaxel on days 1, 8 and 15 of each 21-day cycle for 4 or 6 cycles or until disease progression, whichever occurs first. People received best supportive care during the maintenance treatment phase. Switch maintenance to pemetrexed was also permitted. People who were consented prior to a protocol revision were given the option to crossover to receive Tecentriq as monotherapy until disease progression.

The co-primary endpoints were:

- PFS as determined by the investigator using RECIST v1.1 in all randomised people without an EGFR or ALK mutation (intention-to-treat wild-type; ITT-WT)
- OS in the ITT-WT population

IMpower130 met its OS and PFS co-primary endpoints.

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

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 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.

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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