

Roche's Tecentriq plus chemotherapy (carboplatin and Abraxane) as an initial treatment helped people with advanced non-squamous non-small cell lung cancer live significantly longer compared to chemotherapy alone

- **The Phase III IMpower130 study investigating the Tecentriq plus chemotherapy combination demonstrated a significant overall survival (OS) and progression-free survival (PFS) benefit**
- **Data will be presented at the European Society for Medical Oncology (ESMO) 2018 Congress on 22 October 2018**

Basel, 22 October 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive results from the Phase III IMpower130 study of Tecentriq® (atezolizumab) plus chemotherapy (carboplatin and Abraxane® [albumin-bound paclitaxel; nab-paclitaxel]) for the initial (first-line) treatment of people with previously untreated metastatic non-squamous non-small cell lung cancer (NSCLC). The analysis showed that Tecentriq plus chemotherapy helped people live significantly longer compared to chemotherapy alone (median overall survival [OS] =18.6 versus 13.9 months; hazard ratio [HR]=0.79; 95% CI: 0.64–0.98; p=0.033) in the intention-to-treat wild-type (ITT-WT) population.^[1] The Tecentriq-based combination also significantly reduced the risk of disease worsening or death (progression-free survival; PFS) compared to chemotherapy alone (median PFS=7.0 versus 5.5 months; HR=0.64; 95% CI: 0.54–0.77; p<0.0001) in the ITT- WT population.¹ Safety for the Tecentriq plus chemotherapy combination appeared consistent with the known safety profile of the individual medicines, and no new safety signals were identified with the combination.

“Initial treatment with this Tecentriq-based combination provided a significant survival benefit for people with non-squamous non-small cell lung cancer, the most common form of lung cancer,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Lung cancer is a complex disease and this combination could offer a new potential treatment option. We will work with global health authorities to bring this regimen to people living with this disease as soon as possible.”

The data will be presented at the European Society for Medical Oncology (ESMO) 2018 Congress on 22 October 2018, 09:15–09:30 am; Hall A1 – Room 17 (Abstract LBA53).

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. The study enrolled 723 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 the ITT-WT population
- OS in the ITT-WT population

IMpower130 met its co-primary endpoints of OS and PFS.

A summary of the results is included below:

Arm A (Tecentriq plus chemotherapy) vs Arm B (chemotherapy) in ITT-WT		
	Arm A n=451	Arm B n=228
Median OS, months (95% CI)	18.6 (16.0–21.2)	13.9 (12.0–18.7)
HR (95% CI); P value	0.79 (0.64, 0.98); p=0.033	
1-year OS, % (95% CI)	63.1 (58.59–67.66)	55.5 (48.89–62.17)
Confirmed ORR, % (95% CI)	49.2 (44.49–53.96)	31.9 (25.84–38.36)
Median DOR, months (95% CI)	8.4 (6.9–11.8)	6.1 (5.5–7.9)
Median PFS (95% CI), months	7.0 (6.2–7.3)	5.5 (4.4–5.9)
HR (95% CI); P value	0.64 (0.54, 0.77); p<0.0001	
1-year PFS rate, % (95% CI)	29.1 (24.83–33.44)	14.1 (9.37–18.76)
CI, confidence interval; DOR, duration of response; HR, hazard ratio; ORR, objective response rate; PFS, progression-free survival		

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. Grade 3 - 4 treatment-related adverse events (AEs) were reported in 73.2% of people receiving Tecentriq plus chemotherapy compared to 60.3% of people receiving chemotherapy alone. The most common Grade 3 - 4 AEs in people receiving Tecentriq plus chemotherapy were: an abnormal low count of a certain type of white blood cell (neutropenia, 32.1%), a decrease in red blood cells (anaemia, 29.2%), and a decreased neutrophil count (12.1%).

About NSCLC

Lung cancer is the leading cause of cancer death globally.^[2] Each year 1.76 million people die as a result of the disease; this translates into more than 4,800 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.³ 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.^[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 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

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.

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References

- [1] Capuzzo F et al., IMpower130: Progression-free survival (PFS) and safety analysis from a randomised phase 3 study of carboplatin + nab-paclitaxel (CnP) with or without atezolizumab (atezo) as first-line (1L) therapy in advanced non-squamous NSCLC. Presented at: European Society for Medical Oncology's (ESMO) 2018 Conference on 22 October, 2018, Munich, Germany. Abstract #LBA53
- [2] GLOBOCAN 2018; Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. World Health Organization. Available from: <http://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf>. Accessed October 2018.
- [3] What is non-small cell lung cancer? American Cancer Society. Available from: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html>. Accessed October 2018.

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