

Roche to present new data from its extensive lung cancer programme at the 2018 World Conference on Lung Cancer (WCLC)

- **New and updated pivotal data from the TECENTRIQ lung programme, including overall survival (OS) and progression-free survival (PFS) results from Phase III IMpower133 study in extensive-stage small cell lung cancer**
- **New integrated pivotal results for entrectinib in ROS1 fusion-positive non-small cell lung cancer, including the global Phase II STARTRK-2 basket study**

Basel, 06 September 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data from its broad clinical development programme across different types of lung cancer will be presented at the International Association for the Study of Lung Cancer (IASLC) 2018 World Conference on Lung Cancer (WCLC), taking place from 23–26 September in Toronto, Canada. 10 abstracts have been accepted, including three 'late breakers' and five oral presentations.

“We look forward to presenting new data from our comprehensive lung cancer programme, including new immunotherapy and targeted treatment strategies across different types of lung cancer,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are particularly pleased to be sharing positive TECENTRIQ data in extensive-stage small cell lung cancer, which has seen limited progress in treatment over the last two decades, as well as new pivotal data for our investigational therapy entrectinib for the treatment of ROS1 fusion-positive lung cancer.”

Key presentations

Progression-free survival (PFS) and overall survival (OS) data from the Phase III IMpower133 study of TECENTRIQ plus chemotherapy (carboplatin and etoposide) for the initial (first-line) treatment of people with extensive-stage small cell lung cancer (ES-SCLC) will be presented in the Presidential Symposium. These are the first positive survival data from a Phase III study with an immunotherapy-based combination in the initial treatment of ES-SCLC.

PFS and OS data will be presented from the Phase III IMpower132 study investigating TECENTRIQ plus pemetrexed and platinum-based chemotherapy (cisplatin or carboplatin) in the initial treatment of people with advanced non-squamous NSCLC. The IMpower132 and IMpower133 data will be featured as part of WCLC’s official press programme on Monday 24th and Tuesday 25th of September, respectively.

Additionally, results from a Phase Ib study investigating Tarceva plus TECENTRIQ in tyrosine kinase inhibitor (TKI)-naïve people with EGFR mutation-positive NSCLC will also be presented.

New pivotal results of entrectinib, an investigational oral, CNS-active treatment for people with locally advanced or metastatic ROS1 fusion-positive NSCLC, from a pooled analysis including the global Phase II STARTRK-2 basket study will be presented. These data have also been selected to be featured in the WCLC press programme on Monday 24th of September.

Follow Roche on Twitter via @Roche and keep up to date with WCLC 2018 congress news and updates by using the hashtag #WCLC2018.

For more information on Roche’s approach to cancer, visit Roche.com.

Overview of key presentations featuring Roche medicines at WCLC 2018

Medicine	Abstract title	Abstract number
Entrectinib	Efficacy and safety of entrectinib in locally advanced or metastatic ROS1 fusion-positive NSCLC	OA02.01 Oral Monday 24 September 10:30–10:40 EDT
TECENTRIQ (atezolizumab)	IMpower133: Primary PFS, OS and safety in a phase 1/3 study of 1L atezolizumab plus carboplatin and etoposide in extensive-stage SCLC	PL02.07 Oral Tuesday 25 September 09:00–09:10 EDT
TECENTRIQ (atezolizumab)	IMpower132: PFS, OS and safety results of 1L atezolizumab plus carboplatin/cisplatin plus pemetrexed in stage IV non-squamous NSCLC	OA05.07 Oral Monday 24 September 14:35–14:45 EDT
TECENTRIQ (atezolizumab)	Comprehensive peripheral blood immunophenotyping and T-cell clonal analysis during neoadjuvant immunotherapy with atezolizumab in NSCLC	MA04.10 Mini Oral Monday 24 September 14:35–14:40 EDT
TECENTRIQ (atezolizumab)	Neoadjuvant atezolizumab in resectable non-small cell lung cancer (NSCLC): updated results from a multicenter study	MA04.09 Mini Oral Monday 24 September 14:30–14:35 EDT
TECENTRIQ (atezolizumab) Erlotinib	Long-term safety and clinical activity results from a phase 1b of erlotinib plus atezolizumab in advanced NSCLC	MA15.02 Mini Oral Tuesday 25 September 13:35–13:40 EDT
TECENTRIQ (atezolizumab) Avastin (bevacizumab)	IMpower150: Impact of chemotherapy cycles in 1L metastatic NSCLC in patients treated with atezolizumab and bevacizumab	P1.01-83 Poster Monday 24 September 16:45–18:00 EDT
TECENTRIQ (atezolizumab)	Retrospective descriptive analysis of metformin with atezolizumab in advanced non-small cell lung cancer in the OAK trial	P1.04-33 Poster Monday 24 September 16:45–18:00 EDT
TECENTRIQ (atezolizumab)	IMpower030: Phase III study evaluating neoadjuvant treatment of resectable stage II-IIIB NSCLC with atezolizumab plus chemotherapy	P2.17-27 Poster Tuesday 25 September 16:45–18:00 EDT
TECENTRIQ (atezolizumab)	Cost-Effectiveness of Atezolizumab for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) in Canada	P3.04-17 Poster Wednesday 26 September 12:00–13:00 EDT

About NSCLC and SCLC

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.^[1] Lung cancer can be broadly divided into two major types: non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC is the most prevalent type, accounting for around 85% of all cases,² with SCLC accounting for approximately 15% of all lung cancer cases.^[2] Survival rates for people with SCLC vary depending on the stage (extent) of the cancer at the time of diagnosis.^[3] 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%.^[4]

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 ROS1 fusion-positive non-small cell lung cancer (NSCLC)

ROS1 is a tyrosine kinase, which play a role in controlling how cells grow and proliferate. When a ROS1 gene fusion occurs, 'healthy' cell signalling malfunctions, causing cells to grow and proliferate in an uncontrolled manner – this results in cancer.

ROS1 gene fusions account for 1-2% of NSCLC. Lung cancer is the leading cause of cancer-related death across the world. Each year, 1.59 million people die as a result of the disease; this translates into more than 4,350 deaths worldwide every day.¹ NSCLC is the most prevalent type of lung cancer, accounting for around 85% of all cases.² While the ROS1 gene fusion can be found in any patient with NSCLC, young never-smokers with NSCLC have the highest incidence of ROS1 fusions.

About entrectinib

Entrectinib (RXDX-101) is an investigational, oral medicine in development for the treatment of locally advanced or metastatic solid tumours that harbour NTRK1/2/3 or ROS1 fusions. It is a selective, CNS-active tyrosine kinase inhibitor designed to inhibit the kinase activity of the TRKA/B/C and ROS1 proteins, whose activating fusions drive proliferation in certain types of cancer. Entrectinib can block ROS1 and NTRK kinase activity and may result in the death of cancer cells with ROS1 or NTRK fusions. Entrectinib is being investigated across a range of solid tumour types, including NSCLC, pancreatic cancer, sarcomas, thyroid cancer, salivary cancer, gastrointestinal stromal tumours (GIST) and cancers of unknown primary (CUP).

Entrectinib has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA); Priority Medicines (PRIME) designation by the European Medicines Agency (EMA); and Sakigake designation by the Japanese health authorities for the treatment of NTRK fusion-positive, locally advanced or metastatic solid tumours in adult and paediatric patients who have either progressed following prior therapies or have no acceptable standard therapies.

About Roche in Oncology

Roche has been working to transform cancer care for more than 50 years, bringing the first specifically designed anti-cancer chemotherapy drug, fluorouracil, to patients in 1962. Roche's commitment to developing innovative medicines and diagnostics for cancers remains steadfast.

The Roche Group's portfolio of innovative cancer medicines includes: Alecensa® (alectinib); Avastin® (bevacizumab); Cotellic® (cobimetinib); Erivedge® (vismodegib); Gazyva®/Gazyvaro® (obinutuzumab); Herceptin® (trastuzumab); Kadcyła® (trastuzumab emtansine); MabThera®/Rituxan® (rituximab); Perjeta® (pertuzumab); Tarceva® (erlotinib); Tecentriq® (atezolizumab); Venclexta®/Venclxyto™ (venetoclax); Xeloda® (capecitabine); Zelboraf® (vemurafenib). Furthermore, the Roche Group has a robust investigational oncology pipeline focusing on new therapeutic targets and novel combination strategies.

For more information on Roche's approach to cancer, visit Roche.com.

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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References

- [1] Ferlay J et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide. IARC CancerBase No. 11 [Internet]. Lyon France: International Agency for Research on Cancer; 2013. Available from: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. Accessed August 2018.
- [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; Key Statistics for Small Cell Lung Cancer [Internet]: <https://www.cancer.org/cancer/small-cell-lung-cancer/about/key-statistics.html>. Accessed August 2018.
- [4] American Cancer Society; Small Cell Lung Cancer Survival Rates, by Stage [Internet]: <https://www.cancer.org/cancer/small-cell-lung-cancer/detection-diagnosis-staging/survival-rates.html>. Accessed August 2018.

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