Roche provides update on Phase III study of Tecentriq (atezolizumab) and Cotellic (cobimetinib) in people with heavily pre-treated locally advanced or metastatic colorectal cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMblaze370 study evaluating the combination of Tecentriq® (atezolizumab) and Cotellic® (cobimetinib) did not meet its primary endpoint of overall survival (OS) compared to regorafenib. The study evaluated the combination in people with difficult-to-treat, locally advanced or metastatic colorectal cancer (CRC) whose disease progressed or who were intolerant to at least two systemic chemotherapy regimens.

More than 95% of patients in IMblaze370 have microsatellite stable (MSS) tumours and based on the available data, checkpoint inhibitors as monotherapy have not demonstrated clinically meaningful efficacy in MSS mCRC. The results from IMblaze370 were consistent with this prior monotherapy experience, showing that treatment with Tecentriq alone did not provide a meaningful clinical benefit compared to regorafenib in this patient population.

Safety for the combination of Tecentriq and Cotellic appeared to be consistent with the known safety profiles of the individual medicines, and no new safety signals were identified with the combination. The results from IMblaze370 will be further examined and presented at an upcoming medical meeting.

"While these results are not what we hoped for, we remain committed to applying our deep experience to develop medicines that will improve outcomes for people living with gastrointestinal cancers," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "In particular, we have a number of studies evaluating medicines in colorectal cancer that could play an important role in the treatment of people with this disease in the future."

Roche has an extensive clinical trial development program for Tecentriq, with more than 50 studies ongoing, including multiple Phase III studies across lung, kidney, skin, breast, colorectal, prostate, ovarian, bladder, blood, liver and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines.
About the IMblaze370 study
IMblaze370 is a Phase III, multi-centre, open-label, three-arm, randomised study in people with difficult-to-treat locally advanced or metastatic colorectal cancer who have received at least two prior regimens of chemotherapy for metastatic disease. The study compares regorafenib, a standard of care therapy in this setting, to Cotellic plus Tecentriq and Tecentriq monotherapy. The study enrolled 363 people who were randomised (2:1:1) to receive:

- Tecentriq plus Cotellic, or
- Tecentriq, or
- regorafenib (control arm)

People in the combination arm received Cotellic on days 1 to 21 plus Tecentriq on day 1 and day 15 in a 28-day cycle, until loss of clinical benefit. People in the monotherapy arm received Tecentriq on day 1 of each 21-day cycle, until loss of clinical benefit. People in the control arm received regorafenib on days 1 to 21 in a 28-day cycle, until loss of clinical benefit. The primary endpoint was overall survival. Key secondary endpoints include progression-free survival (PFS), overall response rate (ORR) and duration of response (DoR).

About colorectal cancer
Colorectal cancer (CRC) is caused by the abnormal growth of epithelial cells which form the lining of the colon or rectum. It is the third most common cancer in the world and one of the leading causes of cancer-related death\(^1\). In 2012, approximately 1.4 million new cases of the disease were diagnosed globally and 694,000 deaths were caused by the disease.\(^1\) Although advances in screening have reduced mortality for CRC, 20% of people with CRC have metastatic disease at initial diagnosis.\(^2,3\)

About the Tecentriq and Cotellic combination
Based on our pre-clinical data and Phase Ib data there was a strong scientific rationale to support the further investigation of the combination of Tecentriq and Cotellic. The IMblaze370 data will be further examined in order to better understand the results and presented at an upcoming medical meeting. Roche is continuing to investigate the Tecentriq and Cotellic combination in other tumour types, including the IMspire150 and IMspire170 studies in melanoma.
About Tecentriq (atezolizumab)
TECENTRIQ is a monoclonal antibody designed to bind with a protein called PD-L1. TECENTRIQ is designed to bind to 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 re-activation of T cells. TECENTRIQ may also affect normal cells.

About Cotellic (cobimetinib)
Cotellic is a prescription medicine used with Zelboraf for the treatment of people with a type of skin cancer called melanoma that has spread to other parts of the body or cannot be removed by surgery and has a certain type of abnormal BRAF gene. Cotellic is not used to treat melanoma with a normal BRAF gene. Cotellic was discovered by Exelixis Inc. (Nasdaq: EXEL) and was developed by Roche in collaboration with Exelixis. Cotellic is also being investigated in combination with several in several tumour types such as non-small cell lung cancer, melanoma and colorectal cancer.

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. All trademarks used or mentioned in this release are protected by law.

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References