Media Release

Roche announces positive Phase III study results for Tecentriq plus Cotellic and Zelboraf in people with previously untreated BRAF V600 mutation-positive advanced melanoma

Basel, 13 December 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the Phase III IMspire150 study, in people with previously untreated BRAF V600 mutation-positive advanced melanoma, met its primary endpoint of progression-free survival (PFS). The study showed adding Tecentriq® (atezolizumab) to Cotellic® (cobimetinib) and Zelboraf® (vemurafenib) helped to reduce the risk of disease worsening or death, compared to placebo plus Cotellic and Zelboraf.

A significant and clinically meaningful improvement in PFS was demonstrated in the study. The safety profile observed in IMspire150 was consistent with the known safety profiles of the individual medicines. Results from the study will be presented at an upcoming medical meeting and discussed with health authorities, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

“By combining a cancer immunotherapy with targeted therapies, we hope to offer a new approach that improves outcomes for people with advanced, BRAF-mutant melanoma." said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "We look forward to discussing the results with health authorities around the world.”

Roche has an extensive clinical trial development programme for Tecentriq, with more than 50 ongoing studies, including multiple Phase III studies across lung, kidney, skin, breast, colorectal, prostate, ovarian, bladder, blood, liver and head and neck cancers. Studies are evaluating Tecentriq alone and in combination with other medicines.

About the IMspire150 study
IMspire150 is a Phase III, multi-centre, double-blind, placebo-controlled randomised study in people with previously untreated BRAF V600 mutation-positive metastatic or unresectable locally advanced melanoma. The study compared the efficacy and safety of Tecentriq plus Cotellic and Zelboraf to the combination of placebo plus Cotellic and Zelboraf. The primary endpoint of the study was investigator-assessed PFS. Key secondary endpoints include PFS by an independent review committee, overall survival, objective response rate, duration of response and other safety and pharmacokinetic measures.

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About advanced melanoma
Melanoma is a less common, but more aggressive and potentially deadly form of skin cancer.[1,2,3] When melanoma is diagnosed early, it is generally a curable disease,[4,5] but most people with advanced melanoma have a poor prognosis.[2] More than 287,000 people worldwide are currently diagnosed with melanoma each year.[6] In recent years, there have been significant advances in treatment for advanced melanoma and people with the disease have more options. However, it continues to be a serious health issue with a high medical need and a steadily increasing incidence over the past 30 years.[7]

About Tecentriq (atezolizumab)
Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1, which is 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 is a cancer immunotherapy that has the potential to be used as a foundational combination partner with other immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers. The development of Tecentriq and its clinical programme is based on our greater understanding of how the immune system interacts with tumours and how harnessing a person's immune system combats cancer more effectively.

Tecentriq is approved in the US, EU and countries around the world, either alone or in combination with targeted therapies and/or chemotherapies in various forms of non-small cell and small cell lung cancer, certain types of metastatic urothelial cancer, and in PD-L1-positive metastatic triple-negative breast cancer.

About Cotellic (cobimetinib)
Cotellic is designed to inhibit MEK1/2, proteins in a cell signalling pathway that helps control cell growth and survival. Cotellic, when used in combination with Zelboraf, is approved in the United States and Europe, as well as many countries around the world, for the treatment of people with melanoma that has spread to other parts of the body or cannot be removed by surgery and has a BRAF V600 mutation. Cotellic was discovered by Exelixis and is being developed by Genentech, a member of the Roche Group, in collaboration with Exelixis.

About Zelboraf (vemurafenib)
Zelboraf is a prescription medicine for the treatment of people with melanoma that has spread to other parts of the body or cannot be removed by surgery and has BRAF V600 mutation. Zelboraf is designed to inhibit some mutated forms of BRAF, which cause abnormal signalling inside cancer cells leading to tumour growth. BRAF is a protein in a cell signalling pathway that helps control cell growth and survival. Zelboraf was the first approved product in its class. Zelboraf was co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon Inc., the small molecule structure-guided R&D centre of the Daiichi Sankyo Group.

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. More than 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 eleventh consecutive year, Roche has been recognised as one of the most sustainable companies 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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