Roche's Kadcyla reduced the risk of disease recurring in people with HER2-positive early breast cancer with residual disease after neoadjuvant treatment

- **Phase III KATHERINE study shows Kadcyla significantly improved invasive disease-free survival compared to Herceptin in people with HER2-positive early breast cancer with residual disease after neoadjuvant treatment**
- **Data will be submitted to health authorities around the world, including the US Food and Drug Administration and European Medicines Agency**
- **Results will be presented at the 2018 San Antonio Breast Cancer Symposium in December**

Basel, 15 October 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the phase III KATHERINE study met its primary endpoint, showing Kadcyla® (trastuzumab emtansine) as a single agent significantly reduced the risk of disease recurrence or death (invasive disease-free survival, iDFS) compared to Herceptin® (trastuzumab) as an adjuvant (after surgery) treatment in people with HER2-positive early breast cancer (eBC) who have residual disease (pathological invasive residual disease in the breast and/or axillary nodes) present following neoadjuvant (before surgery) treatment. The safety profile of Kadcyla in the KATHERINE study was consistent with previous clinical trials and no new safety signals were identified. [1,2]

"We are highly encouraged by these positive results with adjuvant Kadcyla treatment in people with HER2-positive early breast cancer who have residual disease after neoadjuvant therapy," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We look forward to discussions with regulatory authorities with the goal of bringing this new treatment option to patients as soon as possible."

Full results will be submitted to health authorities around the world, and will be presented at the 2018 San Antonio Breast Cancer Symposium on Wednesday 5 December at 11.00 am CST.

The KATHERINE trial investigated a population of people with HER2-positive eBC who did not achieve a pathological complete response to neoadjuvant treatment. This state of residual disease is associated with a worse prognosis.[3,4]

The goal in treating early breast cancer is to provide people with the best chance for a cure. [5] While we come closer to this goal with each advance, many people still have a disease recurrence in the long-term. [6] Neoadjuvant treatment is given before surgery with the goal of shrinking tumours and helping to improve surgical outcomes. [7-9] Adjuvant treatment is given after surgery as part of a complete eBC treatment regimen and is aimed at eliminating any remaining cancer cells in the body, to help reduce the risk of the cancer returning. [7]

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About the KATHERINE study[10]
KATHERINE is an international, multi-centre, two-arm, randomised, open-label, phase III study evaluating the efficacy and safety of Kadcyla versus Herceptin as an adjuvant therapy in people with HER2-positive eBC who have pathological residual disease in the breast and/or axillary lymph nodes following neoadjuvant therapy that included Herceptin and taxane-based chemotherapy. The primary endpoint of the study is iDFS which, in this study, is defined as the time from randomisation to invasive breast cancer recurrence or death from any cause. Secondary endpoints include disease-free survival and overall survival.

About Kadcyla
Kadcyla is an antibody-drug conjugate (ADC) engineered to deliver potent chemotherapy directly to HER2-positive cancer cells, potentially limiting damage to healthy tissues. [1,2] It combines two anti-cancer properties joined together by a stable linker: the HER2-targeting properties of trastuzumab (the active ingredient in Herceptin) and the chemotherapy agent DM1. [11] Kadcyla is the only ADC approved as a single agent in 104 countries including the US and EU for the treatment of people with HER2-positive metastatic breast cancer who have previously received Herceptin and taxane chemotherapy, separately or in combination. Roche licenses technology for Kadcyla under an agreement with ImmunoGen, Inc.

About Roche's medicines for HER2-positive breast cancer
Roche has been leading research into the HER2 pathway for over 30 years and is committed to improving the health, quality of life and survival of people with both early and advanced HER2-positive disease. HER2-positive breast cancer is a particularly aggressive form of the disease that affects approximately 15-20% of patients. [12] Roche has developed three innovative medicines that have helped transform the treatment of HER2-positive breast cancer: Herceptin (trastuzumab), Perjeta (pertuzumab) and Kadcyla (trastuzumab emtansine). Eligibility for treatment with Roche's HER2-targeted medicines is determined via a diagnostic test, which identifies people who will likely benefit from these medicines at the onset of their disease.

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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