# *Media Release*

## Roche to present new and updated data for seven approved and investigational medicines across multiple types of breast cancer at the 2019 San Antonio Breast Cancer Symposium

- **Study results reflect advancements in HER2-positive, triple-negative, and hormone receptor-positive breast cancer**
- **Follow-up data from pivotal phase III APHINITY study evaluating Perjeta plus Herceptin and chemotherapy in HER2-positive early breast cancer**
- **Results from phase III FeDeriCa study confirming the non-inferiority of a fixed-dose combination of Perjeta and Herceptin administered under the skin**

Basel, 18 November – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that results from a number of studies from across its growing breast cancer portfolio will be presented at the San Antonio Breast Cancer Symposium (SABCS), from 10-14 December 2019. These data include new results in HER2-positive breast cancer and studies of new molecules in hormone receptor-positive (HR-positive) breast cancer.

"For the past three decades we have remained dedicated to improving outcomes for people with breast cancer," said Levi Garraway, MD, Roche's Chief Medical Officer and Head of Global Product Development. "This sustained commitment is exemplified by new data for our approved and investigational medicines across the spectrum of breast cancer being presented at SABCS this year."

**Key presentations**
New data will be presented from a second interim overall survival (OS) analysis of the phase III APHINITY trial evaluating Perjeta® (pertuzumab) and Herceptin® (trastuzumab) plus chemotherapy (the Perjeta-based regimen), compared to Herceptin and chemotherapy, as an adjuvant treatment for HER2-positive early breast cancer (eBC). This latest interim OS analysis also includes updated descriptive invasive disease-free survival (iDFS) and cardiac safety data.

Roche will also present data from the primary analysis of the phase III FeDeriCa study which evaluated a new investigational fixed-dose combination (FDC) of Perjeta and Herceptin administered as a single subcutaneous (SC) formulation in combination with intravenous (IV) chemotherapy. The FDC is administered under the skin in just minutes, significantly reducing the time spent receiving treatment and providing people with HER2-positive breast cancer a potential new treatment option for faster delivery of the Perjeta-based regimen.

Data will also be presented from studies in HR-positive breast cancer, including findings from early studies investigating Roche's pipeline molecules GDC-9545, a selective oestrogen receptor degrader, and GDC-0077, a selective PI3Kα inhibitor.

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**Overview of Roche studies to be presented at SABCS 2019**

| Medicine(s) | Abstract title | Abstract number (date, time, location of presentation) |
|---|---|---|
| **HER2-positive breast cancer** | | |
| Perjeta and Herceptin | Interim OS analysis of APHINITY (BIG 4-11): a randomised multi-centre, double-blind, placebo-controlled trial comparing chemotherapy plus trastuzumab plus pertuzumab versus chemotherapy plus trastuzumab plus placebo as adjuvant therapy in patients with operable HER2-positive eBC | Abstract GS1-04<br>(Oral)<br>Wednesday 11 December<br>08:45 – 11:15 CST<br>Hall 3 |
| Perjeta and Herceptin | SC trastuzumab and hyaluronidase-oysk with IV pertuzumab and docetaxel in HER2-positive advanced breast cancer (aBC): final analysis of the phase IIIb, multi-centre, open-label, single-arm MetaPHER study | Abstract P1-18-05<br>(Poster)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hall 1 |
| Perjeta and Herceptin | Risk of recurrence and death in patients with early HER2-positive breast cancer who achieve a pathological complete response (pCR) after different types of HER2-targeted therapy: a retrospective exploratory analysis | Abstract P1-18-01<br>(Poster)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hall 1 |
| Perjeta and Herceptin | Use of pertuzumab in combination with taxanes for HER2-positive aBC: analysis of US electronic health records | Abstract P1-18-14<br>(Poster)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hall 1 |
| Kadcyla® (trastuzumab emtansine) | Cardiac events in patients with HER2-positive aBC who have low left ventricular ejection fraction prior to initiating treatment with trastuzumab emtansine: a retrospective cohort study using electronic health record data | Abstract P1-18-11<br>(Poster)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hall 1 |
| Tecentriq® (atezolizumab), Kadcyla, Perjeta and Herceptin | Atezolizumab in combination with trastuzumab emtansine or with trastuzumab and pertuzumab in patients with HER2-positive breast cancer and atezolizumab with doxorubicin and cyclophosphamide in HER2-negative breast cancer: safety and biomarker outcomes from a multi-cohort phase Ib study | Abstract PD1-05<br>(Poster discussion)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hemisfair Ballroom |
| Perjeta and Herceptin | SC administration of the FDC of trastuzumab and pertuzumab in combination with chemotherapy in HER2-positive eBC: primary | Abstract PD4-07<br>(Poster discussion)<br>Thursday 12 December |

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| | analysis of the phase III, multi-centre, randomised, open-label, two-arm FeDeriCa study | 07:00 – 09:00 CST<br>Stars at Night Ballroom 1&2 |
| Kadcyla and Perjeta | Association of immune gene expression with outcome in the MARIANNE phase III clinical trial in HER2-positive aBC | Abstract PD5-11<br>(Poster discussion)<br>Thursday 12 December<br>07:00 – 09:00 CST<br>Stars at Night Ballroom 3&4 |
| Kadcyla and Herceptin | Adjuvant trastuzumab emtansine versus trastuzumab in patients with residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer: KATHERINE subgroup analysis | Abstract P3-14-01<br>(Poster)<br>Thursday 12 December<br>17:00 – 19:00 CST<br>Hall 1 |
| Herceptin | Palbociclib in combination with trastuzumab and endocrine therapy versus treatment of physician's choice in advanced HER2-positive and HR-positive breast cancer with PAM50 luminal intrinsic subtype (SOLTI-1303 PATRICIA II): a multi-centre, randomised, open-label, phase II trial | Abstract OT2-02-06<br>(Poster)<br>Thursday 12 December<br>17:00 – 19:00 CST<br>Hall 1 |
| Kadcyla and Herceptin | Cost-effectiveness of trastuzumab emtansine versus trastuzumab for the adjuvant treatment of patients with residual invasive HER2-positive eBC in the US | Abstract P6-13-01<br>(Poster)<br>Saturday 14 December<br>07:00 – 09:00 CST<br>Hall 1 |
| **Hormone receptor-positive** | | |
| GDC-0077 | A first-in-human phase Ia dose escalation study of GDC-0077, a p110a-selective and mutant-degrading PI3K inhibitor, in patients with PIK3CA-mutant solid tumors | Abstract OT1-08-04<br>(Poster)<br>Wednesday 11 December<br>17:00 – 19:00 CST |
| GDC-0077 | A phase Ib dose escalation study evaluating the mutant selective PI3K-alpha inhibitor GDC-0077 in combination with letrozole with and without palbociclib in patients with PIK3CA-mutant HR-positive, HER2-negative breast cancer | Abstract P1-19-46<br>(Poster)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hall 1 |
| GDC-9545 | A first-in-human phase I study to evaluate the oral selective estrogen receptor degrader (SERD), GDC-9545, in postmenopausal women with HR-positive/HER2-negative aBC | Abstract PD7-05<br>(Poster discussion)<br>Thursday 12 December<br>17:00 – 19:00 CST<br>Stars at Night Ballroom 1&2 |
| **Triple-negative breast cancer (TNBC)** | | |

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| Tecentriq | Exploratory analytical harmonisation of PD-L1 immunohistochemistry assays in advanced TNBC: a retrospective substudy of IMpassion130 | Abstract PD1-07<br>(Poster discussion)<br>Wednesday 11 December<br>17:00 – 19:00 CST<br>Hemisfair Ballroom |
| Tecentriq | Systemic corticosteroid use in patients with metastatic TNBC treated with first-line therapy in the US | Abstract P2-15-09<br>(Poster)<br>Thursday 12 December<br>07:00 – 09:00 CST<br>Hall 1 |
| Ipatasertib | Expression of PD-L1 is independent of *PIK3CA/AKT1/PTEN* alterations in TNBC and is not associated with response to ipatasertib plus paclitaxel | Abstract P4-10-23<br>(Poster)<br>Friday 13 December<br>07:00 – 9:00 CST<br>Hall 1 |

**About the APHINITY study** [1,2]

APHINITY (Adjuvant Pertuzumab and Herceptin IN Initial TherapY in Breast Cancer, NCT01358877/ BO25126/ BIG 4-11) is an international, phase III, randomised, double-blind, placebo-controlled, two-arm study evaluating the efficacy and safety of Perjeta plus Herceptin and chemotherapy, compared to Herceptin and chemotherapy, as adjuvant therapy in 4,805 people with operable HER2-positive eBC. The primary efficacy endpoint of the APHINITY study is iDFS, which in this study is defined as the time a patient lives without return of invasive breast cancer at any site or death from any cause after adjuvant treatment. Secondary endpoints include cardiac and overall safety, OS, disease-free survival and health-related quality of life. The study will continue to follow participants for ten years..

**About the FeDeriCa study** [3]

FeDeriCa is an international, multi-centre, two-arm, randomised, open-label, phase III study evaluating the pharmacokinetics, efficacy and safety of SC injection of the FDC of Perjeta and Herceptin in combination with chemotherapy, compared with standard IV infusions of Perjeta and Herceptin in combination with chemotherapy, in people with HER2-positive eBC who are being treated in the neoadjuvant (before surgery) and adjuvant (after surgery) settings. The primary endpoint of the study is minimum levels of Perjeta in the blood during a given dosing interval (Ctrough). Secondary endpoints include safety; minimum levels of Herceptin in the blood during a given dosing interval (Ctrough); and total pCR, meaning there is no tumour tissue detectable at the time of surgery.

**About Roche in breast cancer**

Roche has been advancing breast cancer research for more than 30 years with the goal of helping as many people with the disease as possible. Our medicines, along with companion diagnostic tests, have contributed to bringing breakthrough innovations in HER2-positive breast cancer which have changed the natural history of the disease. As our understanding of breast cancer biology has rapidly evolved, we have expanded our focus to identify new biomarkers and approaches to treatment for other types of breast cancer, such as triple-negative and HR-positive disease, where there remains a significant unmet need.

Our HER2-targeted medicines Herceptin, Perjeta and Kadcyla continue to transform the treatment of early and advanced HER2-positive breast cancer and now, through our large clinical trial programmes with Tecentriq and ipatasertib and recent approvals for Tecentriq, we are bringing new treatment options to people with TNBC.

**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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**References**

[1] ClinicalTrials.gov. A Study of Pertuzumab in Addition to Chemotherapy and Trastuzumab as Adjuvant Therapy in Participants With Human Epidermal Growth Receptor 2 (HER2)-Positive Primary Breast Cancer (APHINITY). [Internet; cited November 2019]. Available from: https://clinicaltrials.gov/ct2/show/NCT01358877.
[2] Minckwitz G, et al. N Engl J Med. 2017;377:122-31.
[3] Clinical trials.gov. A Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Combination With Chemotherapy in Participants With HER2-Positive Early Breast Cancer. [Internet; cited November 2019]. Available from: https://clinicaltrials.gov/ct2/show/NCT03493854.

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