

## **European Commission approves Roche's Kadcyła for the adjuvant treatment of people with HER2-positive early breast cancer with residual invasive disease after neoadjuvant treatment**

- **Kadcyła in early breast cancer represents a new option after neoadjuvant treatment for this group of patients who are known to have a worse prognosis**
- **Approval based on KATHERINE trial data showing Kadcyła cut the risk of disease recurrence or death by half compared to Herceptin in the adjuvant setting**

Basel, 19 December 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Commission has approved Kadcyła® (trastuzumab emtansine) for the adjuvant (after surgery) treatment of adult patients with HER2-positive early breast cancer (eBC) who have residual invasive disease in the breast and/or lymph nodes after neoadjuvant (before surgery) taxane-based and HER2-targeted therapy.

“Optimal treatment is vital for every patient with early-stage breast cancer, a setting where cures are possible,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “This approval of Kadcyła will allow many more women with HER2-positive early breast cancer to be given a transformative treatment that may cut the risk of their disease returning or progressing.”

The goal of neoadjuvant treatment is to shrink tumours in order to help improve surgical outcomes. Adjuvant treatment aims to eliminate any remaining cancer cells in the body to help reduce the risk of the cancer returning.<sup>1</sup> People who have residual disease after neoadjuvant treatment have a worse prognosis than those with no detectable disease.<sup>2</sup>

The approval of Kadcyła in Europe is based on results from the phase III KATHERINE study, which showed that Kadcyła significantly reduced the risk of invasive breast cancer recurrence or death from any cause (invasive disease-free survival; iDFS) by 50% (HR=0.50, 95% CI 0.39-0.64, p<0.001) compared to Herceptin® (trastuzumab) as an adjuvant treatment in people with HER2-positive eBC who have residual invasive disease after neoadjuvant taxane and Herceptin-based treatment. At three years, 88.3% of people treated with Kadcyła did not have their breast cancer return compared to 77.0% treated with Herceptin, an absolute improvement of 11.3%. The safety profile of Kadcyła was consistent with that observed in previous studies.<sup>3</sup>

The impact of adjuvant treatment with Kadcyła has already been seen in the US where thousands of women are already being given this treatment following US Food and Drug Administration approval in May.<sup>4</sup> Kadcyła in this setting is now approved in 27 countries worldwide and the use of Kadcyła in eBC has been recommended by multiple treatment guidelines, including those from the St Gallen International Breast Cancer Conference, the AGO and the NCCN.<sup>5,6,7</sup>

### About the KATHERINE study<sup>8</sup>

KATHERINE is an international, multi-centre, two-arm, randomised, open-label, phase III study evaluating the efficacy and safety of Kadcyła versus Herceptin as an adjuvant therapy in people with HER2-positive eBC who have pathological invasive 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 the time that the patient is free from invasive breast cancer recurrence, or death from any cause. Secondary endpoints include iDFS including second primary non-breast cancer, disease-free survival and overall survival.

<b>KATHERINE study results<sup>3</sup></b>		
	<b>Kadcyła</b> n=743	<b>Herceptin</b> n=743
<b>Median follow-up</b>	~41 months	
<b>iDFS</b>		
<b>Risk reduction</b>	HR=0.50, 95% CI 0.39-0.64, p<0.001	
<b>3-year iDFS</b>	88.3%	77.0%
	11.3% absolute improvement	
<b>Adverse events (AEs)</b>		
<b>Grade ≥3AEs</b>	25.7%	15.4%
<b>Most common Grade ≥3 AEs (≥1%)</b>		
<b>Thrombocytopenia</b> (decreased platelet count)	5.7%	0.3%
<b>Hypertension</b> (high blood pressure)	2.0%	1.2%

### About Kadcyła

Kadcyła is an antibody-drug conjugate (ADC) engineered to deliver potent chemotherapy directly to HER2-positive cancer cells, potentially limiting damage to healthy tissues. 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.<sup>9</sup> Kadcyła is the only ADC approved as a single agent in over 100 countries, including the US and EU, for the treatment of people with HER2-positive metastatic breast cancer who have previously received Herceptin and taxane-based chemotherapy, separately or in combination. Kadcyła is also approved in the US for the adjuvant treatment of people with HER2-positive eBC with residual invasive disease after neoadjuvant treatment that included Herceptin and taxane-based chemotherapy. Roche licenses technology for Kadcyła 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 breast cancer.

HER2-positive breast cancer is a particularly aggressive form of the disease that affects approximately 15-20% of patients.<sup>10</sup> Roche has developed three innovative medicines that have helped transform the treatment of HER2-positive breast cancer: Herceptin® (trastuzumab), Perjeta® (pertuzumab) and Kadcyła® (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. 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](http://www.roche.com).

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