Media & Investor Release

FDA approves Roche's Wilserdly (giredestrant) for early-stage ER-positive breast cancer, making it the first new endocrine therapy in this setting in over 20 years

- **Approval is based on the landmark phase III lidERA study, where Wilserdly reduced the risk of invasive disease recurrence or death by 30% versus standard endocrine therapy, including tamoxifen and aromatase inhibitors, with a favourable safety profile[1]**
- **Wilserdly, a next-generation oral SERD, is now the first and only SERD FDA-approved in both early-stage and advanced ER-positive breast cancer, with the potential to become a standard of care across settings**
- **Approximately 225,000 women in the US are diagnosed annually with HR-positive, HER2-negative breast cancer and 90% will be diagnosed in the early-stage, where the opportunity for cure is highest[2-7]**
- **Roche continues to invest in the broad development of Wilserdly, exploring its potential as a backbone across different stages of breast cancer and in novel treatment combinations, with the ambition to improve outcomes for more people affected by the disease**

Basel, 23 November 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the United States (U.S.) Food and Drug Administration (FDA) has approved Wilserdly™ (giredestrant) as a single agent for the adjuvant treatment of adults with oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, stage I, II, and III breast cancer at intermediate to high risk of recurrence.

"This FDA approval marks Wilserdly as the first SERD approved for ER-positive early-stage breast cancer, having demonstrated superior efficacy against tamoxifen and aromatase inhibitors, which defined the standard of care for decades," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "By addressing a critical need in early-stage disease, where the chance for cure is greatest, Wilserdly has the potential to establish an important new standard of care for patients and physicians."

This approval is supported by the landmark phase III lidERA study, where adjuvant Wilserdly reduced the risk of invasive disease recurrence or death by 30% compared with standard endocrine therapy, including tamoxifen and aromatase inhibitors (stratified hazard ratio [HR]=0.70; 95% confidence interval [CI]: 0.57–0.87; p=0.0014).[1] Overall survival data were immature at the time of this analysis, but a clear positive trend was observed.[1] Patients treated with Wilserdly demonstrated lower overall treatment discontinuation rates due to adverse events compared to standard endocrine options (5.3% vs. 8.2%).[1]

“For clinicians treating ER-positive early-stage breast cancer, the goal is not only to treat the disease we see today, but to reduce the risk of it returning in the years ahead,” said Aditya Bardia, MD, MPH, Global Principal Investigator of the lidERA Breast Cancer trial, and Professor of Medicine at the David Geffen School of Medicine at University of California, Los Angeles (UCLA), Director of Translational Research Integration at the UCLA Health Jonsson Comprehensive Cancer Center. “In lidERA, patients treated with giredestrant had a reduced risk of invasive disease recurrence, as well as fewer treatment discontinuations due to adverse events compared to standard endocrine therapy, thus representing a major clinical advance for patients with breast cancer.”

This follows the recent FDA approval of Wilserdly in combination with everolimus for the treatment of adults with ER-positive, HER2-negative, *ESR1*-mutated locally advanced or metastatic breast cancer, as detected by an FDA-authorised test, whose disease has recurred during or after completion of endocrine-based adjuvant therapy, or has progressed on at least one endocrine-based regimen in the metastatic setting. Wilserdly now stands as the first and only selective oestrogen receptor degrader (SERD) approved in both early-stage and advanced breast cancer.

“Our ambition is for Wilserdly to become a backbone endocrine therapy across both early-stage and advanced ER-positive breast cancer, and these two approvals represent an important step towards achieving this,” said Teresa Graham, Chief Executive Officer, Roche Pharmaceuticals. “We will continue to invest in the broad development of Wilserdly, exploring its potential across different stages of the disease and in new treatment combinations, with the ultimate goal of improving outcomes for more people affected by breast cancer.”

"Progress in breast cancer treatment is measured in breakthroughs that give patients and their families more precious time. Even with all the progress we've achieved, the need for new treatment options remains critical,” said Amber Guild, President and CEO of Susan G. Komen, a US-based breast cancer foundation. “We are energised by what this new treatment option can offer patients, which underscores why we must keep pushing the boundaries of science until no one has to fear a breast cancer diagnosis."

Roche’s broad and robust Wilserdly clinical development programme spans distinct treatment settings and lines of therapy, reflecting our commitment to deliver innovative medicines to as many people with HR-positive breast cancer as possible. Additional regulatory filings and development activities are underway in markets outside the US.

About the lidERA Breast Cancer study

lidERA Breast Cancer [NCT04961996] is a phase III, randomised, open-label, multicentre study evaluating the efficacy and safety of adjuvant Wilserdly™ (giredestrant) monotherapy versus standard endocrine therapy in people with medium- or high-risk stage I-III oestrogen receptor-positive, human epidermal growth factor receptor 2-negative breast cancer.[8] Over 4,100 patients were enrolled in the study.[8]

The primary endpoint is invasive disease-free survival (iDFS) excluding unrelated cancers in other organs (second primary non-breast cancers).[8] Key secondary endpoints include overall survival, iDFS including second primary non-breast cancers, disease-free survival and safety.[8]

About Wilserdly™ (giredestrant)

Wilserdly is a next-generation, potent, oral selective oestrogen receptor degrader (SERD) and full antagonist designed to achieve deep and sustained inhibition of oestrogen receptor (ER) signalling.[9] Wilserdly is designed to block oestrogen from binding to the ER, triggering the breakdown of the ER protein (known as degradation) and stopping or slowing down the growth of cancer cells.[10]

Pre-clinical data have demonstrated improved clinical potency versus other oral SERDs potentially enabling treatment at one of the lowest doses among oral SERDs.[11,12]

Wilserdly has an extensive clinical development programme including six company-sponsored phase III clinical trials across multiple treatment settings and lines of therapy:

Study	Intervention	Patient population
Positive primary study readouts completed		
lidERA Breast Cancer; NCT04961996	Wilserdly versus standard endocrine therapy as adjuvant treatment[8]	ER-positive, human epidermal growth factor receptor 2 (HER2)-negative early-stage breast cancer[8]
evERA Breast Cancer; NCT05306340	Wilserdly plus everolimus versus standard endocrine therapy plus everolimus[13]	ER-positive, HER2-negative, locally advanced or metastatic breast cancer[13]
Primary study readouts pending		
pionERA Breast Cancer; NCT06065748	Wilserdly plus investigator's choice of a cyclin-dependent kinase (CDK)4/6 inhibitor versus fulvestrant plus an investigator's choice CDK4/6 inhibitor[14]	ER-positive, HER2-negative advanced breast cancer resistant to adjuvant endocrine therapy[14]

Study	Intervention	Patient population
heredERA Breast Cancer; NCT05296798	Wilserdly plus Phesgo® (pertuzumab, trastuzumab, and hyaluronidase subcutaneous) versus Phesgo plus optional standard endocrine therapy at investigator's discretion[15]	ER-positive, HER2-positive locally advanced or metastatic breast cancer[15]
novERA Breast Cancer; NCT07541079	Wilserdly, evaluating adherence, tolerability, and patient-reported outcomes[16]	Patients with ER-positive, HER2-negative early-stage breast cancer who are intolerant to adjuvant aromatase inhibitor treatment[16]
kalitERA; NCT07827573	Wilserdly, evaluating treatment adherence, tolerability, and patient-reported outcomes[17]	ER-positive, HER2-negative early-stage breast cancer[17]

About hormone receptor (HR)-positive breast cancer

Globally, the burden of breast cancer continues to grow, with 2.3 million women diagnosed and 670,000 dying from the disease every year.[18] Breast cancer remains the number one cause of cancer-related deaths amongst women, and the second most common cancer type.[19]

HR-positive, human epidermal growth factor receptor 2-negative breast cancer accounts for approximately 70% of breast cancer cases and more than 90% are diagnosed in the early-stage.[4-7,20] A defining feature of HR-positive breast cancer is that its tumour cells have receptors that attach to hormones like oestrogen, which can contribute to tumour growth.[21]

Despite treatment advances, HR-positive breast cancer remains particularly challenging to treat due to its biological complexity.[22] Patients often face the risk of disease progression, treatment side effects and resistance to endocrine therapy.[22,23] There is an urgent need for more effective treatments that can delay clinical progression and reduce the burden of treatment on people's lives.[22,23]

About Roche in breast cancer

Roche has been advancing breast cancer research for more than 30 years, and it continues to be a major focus of research and development. Our legacy includes setting and redefining standards of care with pioneering treatments such as Herceptin® (trastuzumab), Kadcyla® (trastuzumab emtansine) and Phesgo® (pertuzumab, trastuzumab, and hyaluronidase subcutaneous), and we continue to build on this with next-generation innovations such as Itovebi® (inavolisib) and Wilserdly™ (giredestrant), pushing the boundaries of science to address the complexities of all breast cancer subtypes.

By leveraging our dual expertise in pharmaceuticals and diagnostics, we are dedicated to providing tailored treatment approaches and improving outcomes for every patient, from early to advanced stages of the disease. Together with our partners, we are relentlessly pursuing a cure, as we strive for a future where no one dies from breast cancer.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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Roche Global Media Relations

Phone: +41 61 688 88 88 / e-mail: media.relations@roche.com

Tristan Schmitz
Phone: +41 79 529 70 35

Lorena Corfas
Phone: +41 79 568 24 95

Karsten Kleine
Phone: +41 79 461 86 83

Yvette Petillon
Phone: +41 79 961 92 50

Albert Thottiyil
Phone: +41 79 775 66 12

Nathalie Altermatt
Phone: +41 79 771 05 25

Simon Goldsborough
Phone: +44 797 32 72 915

Kirti Pandey
Phone: +41 79 398 38 53

Irène Stephan
Phone: +41 79 377 83 75

Roche Investor Relations

Dr Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com