Media & Investor Release

FDA accepts New Drug Application for Roche's giredestrant in ER-positive early-stage breast cancer, the first and only oral SERD with positive phase III results in the curative setting

- **Filing acceptance, under priority review, based on phase III data showing giredestrant reduced the risk of invasive disease recurrence or death by 30% compared with standard-of-care endocrine therapy[1]**
- **Giredestrant represents the first significant advance in adjuvant endocrine therapy in over 20 years[1-3]**
- **Giredestrant has the potential to become a new standard-of-care in the adjuvant setting; more than 90% of ER-positive breast cancer cases are diagnosed at an early-stage (I-III)[4-7]**
- **The FDA has set a Prescription Drug User Fee Act date of 30 November 2026**

Basel, 02 June 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the United States (US) Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) under Priority Review for giredestrant, an investigational oral selective oestrogen receptor degrader (SERD), as an adjuvant treatment for adults with oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, stage I, II, and III breast cancer. The FDA is expected to make a decision on the approval by 30 November 2026.

"Giredestrant represents the first major endocrine therapy advance in early-stage ER-positive breast cancer in decades, where the chance for cure is highest," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The FDA's filing acceptance brings us closer to delivering a new standard-of-care with the potential to fundamentally change the treatment paradigm for people with early-stage disease."

The filing acceptance is based on the phase III lidERA Breast Cancer study results, which showed adjuvant giredestrant significantly reduced the risk of invasive disease recurrence or death (iDFS) by 30% compared with standard-of-care endocrine therapy (SoC ET) (hazard ratio [HR]=0.70, 95% confidence interval [CI] 0.57-0.87, p=0.0014).[1] At three years, 92.4% of patients in the giredestrant arm were alive and free of invasive disease versus 89.6% in the SoC ET arm.[1] The iDFS benefit was consistent across all clinically relevant subgroups.[1] Overall survival (OS) data were immature at the time of this analysis, but a clear positive trend was observed.[1] Follow-up for OS will continue to the next analysis. Giredestrant was well tolerated; adverse events were manageable and consistent with its known safety profile.[1] The treatment discontinuation rate for giredestrant was 5.3% versus 8.2% with SoC ET.[1]

Additional analyses from the giredestrant programme were presented at the 2026 American Society of Clinical Oncology Congress. This growing body of evidence continues to reinforce the clinical benefit profile of giredestrant and its potential to meaningfully improve outcomes across ER-positive early-stage and advanced breast cancer.

The US FDA recently accepted the NDA for giredestrant in combination with everolimus for those with *ESR1*-mutated, ER-positive advanced breast cancer based on the evERA results, with a decision expected in December 2026.

Roche's expanding giredestrant clinical development programme spans distinct treatment settings and lines of therapy, reflecting our commitment to deliver innovative medicines to as many people with ER-positive breast cancer as possible.

Globally, 2.3 million people are diagnosed with breast cancer each year.[8] ER-positive breast cancer accounts for approximately 70% of breast cancer cases, and the majority are diagnosed in the early-stage.[9,10] Currently, up to a third of people eventually experience recurrence on or after adjuvant endocrine therapy treatment for early-stage breast cancer.[10-12] Additionally, many have to interrupt or stop treatment early due to safety or tolerability issues, thereby increasing the risk of death.[13,14] These limitations underscore the need for more effective and better-tolerated options that can enhance adherence and prevent or delay disease recurrence.

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 giredestrant versus standard-of-care endocrine therapy in people with medium- or high-risk stage I-III oestrogen receptor-positive, human epidermal growth factor receptor 2-negative breast cancer.[15] Over 4,100 patients were enrolled in the study.[15]

The primary endpoint is invasive disease-free survival (iDFS) excluding unrelated cancers in other organs (second primary non-breast cancers).[15] Key secondary endpoints include overall survival, iDFS including second primary non-breast cancers, disease-free survival and safety.[15]

About giredestrant

Giredestrant is an investigational, oral, potent next-generation selective oestrogen receptor degrader and full antagonist.[16]

Giredestrant is designed to block oestrogen from binding to the oestrogen receptor, triggering its breakdown (known as degradation) and stopping or slowing down the growth of cancer cells.[17]

Giredestrant has an extensive clinical development programme and is being investigated in five company-sponsored phase III clinical trials that span multiple treatment settings and lines of therapy to benefit as many people as possible:

- Giredestrant versus standard-of-care endocrine therapy (SoC ET) as adjuvant treatment in oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative early-stage breast cancer (lidERA Breast Cancer; NCT04961996)[15]
- Giredestrant plus everolimus versus SoC ET plus everolimus in ER-positive, HER2-negative, locally advanced or metastatic breast cancer (evERA Breast Cancer; NCT05306340)[18]
- Giredestrant plus palbociclib versus letrozole plus palbociclib in ER-positive, HER2-negative, endocrine-sensitive, recurrent locally advanced or metastatic breast cancer (persevERA Breast Cancer; NCT04546009)[19]
- Giredestrant plus investigator's choice of a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor versus fulvestrant plus a CDK4/6 inhibitor in ER-positive, HER2-negative advanced breast cancer resistant to adjuvant endocrine therapy (pionERA Breast Cancer; NCT06065748)[20]
- Giredestrant plus Phesgo® (pertuzumab, trastuzumab, and hyaluronidase subcutaneous) versus Phesgo in ER-positive, HER2-positive locally advanced or metastatic breast cancer (heredERA Breast Cancer; NCT05296798)[21]

About oestrogen receptor (ER)-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.8 Breast cancer remains the number one cause of cancer-related deaths amongst women, and the second most common cancer type.[22]

ER-positive breast cancer accounts for approximately 70% of breast cancer cases, and the majority are diagnosed in the early-stage.9 A defining feature of ER-positive breast cancer is that its tumour cells have receptors that attach to oestrogen, which can contribute to tumour growth.[23]

Despite treatment advances, ER-positive breast cancer remains particularly challenging to treat due to its biological complexity.[24] Patients often face the risk of disease progression, treatment side effects and resistance to endocrine therapy.[24, 25] There is an urgent need for more effective treatments that can delay clinical progression and reduce the burden of treatment on people's lives.[24, 25]

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 began with the development of the first targeted therapy for human epidermal growth factor receptor 2-positive breast cancer, and we continue to push 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 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Lorena Corfas
Phone: +41 79 568 24 95

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +41 79 398 38 53

Yvette Petillon
Phone: +41 79 961 92 50

Dr Rebekka Schnell
Phone: +41 79 205 27 03

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

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

Investor Relations North America

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