# Media & Investor Release

## Roche to present new data at ASCO 2026, reinforcing giredestrant's potential to transform the treatment paradigm in early breast cancer

- **New giredestrant data from the lidERA study on its potential as a new standard of care for adjuvant ER-positive breast cancer across all menopausal stages**
- **Primary results from the persevERA study on the numerical improvement in progression-free survival observed with first-line giredestrant plus palbociclib in advanced, endocrine-sensitive disease**
- **Overall, nine approved and investigational medicines, including bispecific antibodies, antibody-drug conjugates and brain-permeable molecules, with ASCO data targeting urgent needs in breast, blood, lung and other cancers**

Basel, 19 May 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) will present new data from nine approved and investigational medicines across more than 15 indications at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting, held 29 May to 2 June in Chicago.

"Roche's ASCO data reflect our commitment to addressing those cancers that impose the highest burden on patients and society," said Levi Garraway, MD, PhD, Roche's chief medical officer and head of Global Product Development. "In particular, our ASCO data highlight significant advances in breast cancer, including the latest results for giredestrant and our evolving approach to HER2-positive metastatic disease."

### Redefining the standard of care in breast cancer

Roche's ASCO 2026 focus is on giredestrant, an investigational, oral, selective oestrogen receptor degrader (SERD) being studied in early and advanced oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

This subtype accounts for approximately 70% of breast cancer cases, and the majority are diagnosed in the early stage.[1,2] Data from three phase III trials demonstrate giredestrant's potential as a future standard of care endocrine therapy across multiple disease stages:

- **lidERA Breast Cancer**: Building on the transformational results shared in December 2025, which demonstrated a 30% reduction in the risk of invasive disease recurrence or death,[3] new data will indicate whether the efficacy and safety of giredestrant remain consistent across pre- and post-menopausal patients with early breast cancer. The lidERA data have been submitted to the U.S. Food and Drug Administration (FDA).
- **persevERA Breast Cancer**: Primary results investigating giredestrant in combination with palbociclib as a first-line therapy in locally advanced or metastatic cancer will be presented. These data will provide context following the announcement that while the

study did not meet its primary endpoint, the giredestrant combination showed a numerical improvement in this distinct patient population, suggesting that giredestrant is active in the first-line setting.

- **evERA Breast Cancer**: New post-progression treatment analyses will be shared exploring the sustained clinical benefit for people treated with giredestrant plus everolimus in the post-cyclin-dependent kinase 4/6 inhibitor setting. The U.S. FDA recently accepted the New Drug Application for giredestrant based on the positive evERA data.

Our ASCO data also highlight progress in HER2-positive breast cancer, an area Roche has led for over 30 years:

- **RG6596/ZN-A-1041 in HER2-positive breast cancer**: Preliminary results from a phase Ic expansion trial will provide early information on the safety and efficacy of ZN-A-1041, a highly blood-brain barrier-permeable, HER2-selective tyrosine kinase inhibitor, in combination with other HER2-targeted therapies, for patients with pre-treated HER2-positive metastatic breast cancer. Designed for enhanced brain penetration, ZN-A-1041 may improve the ability to prevent and treat brain metastases, a major challenge in metastatic breast cancers.

## Advancing precision medicine and novel combinations

Roche is also presenting data from its diverse pipeline targeting specific genetic drivers and difficult-to-treat cancers, including:

- **Divarasib in non-small cell lung cancer (NSCLC):** Roche will present results from the Krascendo 170 phase Ib/II study evaluating the next-generation oral KRAS G12C inhibitor divarasib combined with pembrolizumab in treatment-naive patients with KRAS G12C+ advanced NSCLC. These data informed the phase III Krascendo 2 study, which investigates this combination as a first-line therapy regardless of PD-L1 status. Divarasib is currently being evaluated in three pivotal phase III studies as a monotherapy or in chemotherapy-free combinations.

- **Lunsumio® (mosunetuzumab) plus Polivy® (polatuzumab vedotin) in diffuse large B-cell lymphoma (DLBCL)**: Roche will present updated data from the phase III SUNMO trial to further establish the efficacy and safety of Lunsumio plus Polivy compared to chemotherapy (R-GemOx) particularly in second-line patients with relapsed/refractory DLBCL who are not eligible for transplant. This first combination of a bispecific antibody and antibody-drug conjugate could potentially provide patients who often face poor prognoses and significant treatment burdens with an effective, fixed-duration, chemotherapy-free regimen.

**Overview of key presentations featuring Roche medicines and molecules:**

| Medicine or molecule | Abstract title | Abstract number/ presentation details |
|---|---|---|
| **Breast cancer** | | |
| Giredestrant | Giredestrant (GIRE) + palbociclib (PALBO) vs letrozole (LET) + PALBO as first-line (1L) therapy in patients (pts) with estrogen receptor-positive, HER2-negative locally advanced or metastatic breast cancer (ER+, HER2– LA/mBC): Primary analysis of the phase III persevERA Breast Cancer (BC) trial | #LBA1006 oral<br>Breast Cancer – Metastatic<br>Tuesday 02 June 2026 11:45 - 11:57 AM CDT |
| Giredestrant | Efficacy and safety of giredestrant (GIRE) in patients (pts) with estrogen receptor-positive, HER2-negative early breast cancer (ER+, HER2– eBC) in the phase III lidERA BC clinical trial: Results by menopausal status | #502 oral<br>Breast Cancer – Local/Regional/Adjuvant<br>Saturday 30 May 2026 1:39 - 1:51 PM CDT |
| Giredestrant | Post-progression treatment (tx) analyses of evERA Breast Cancer (BC): A phase III trial of giredestrant (GIRE) + everolimus (E) in patients (pts) with estrogen receptor-positive, HER2-negative advanced BC (ER+, HER2– aBC) previously treated with a CDK4/6 inhibitor (i) | #1016 rapid oral<br>Breast Cancer – Metastatic<br>Sunday 31 May 2026 12:00 - 12:06 PM CDT |
| RG6596/ ZN-A-1041 | Safety and efficacy of ZN-A-1041, a highly blood–brain barrier (BBB)-permeable HER2 tyrosine kinase inhibitor (TKI), + trastuzumab deruxtecan (T-DXd) or pertuzumab-trastuzumab (PH) in HER2-positive metastatic breast cancer (HER2+ mBC): Phase Ic expansion results from the ZN-A-1041-101-US trial | #1055 poster<br>Breast Cancer – Metastatic<br>Monday 01 June 2026 1:30 - 4:30 PM CDT |
| Itovebi® (inavolisib) | Outcomes by lobular (lob) histology status at initial diagnosis in patients (pts) in the INAVO120 phase 3 trial with *PIK3CA*-mutated (mut), hormone receptor-positive (HR+), HER2-negative (HER2–), endocrine-resistant advanced breast cancer (aBC) treated with inavolisib (INAVO)/placebo (PBO) + palbociclib (PALBO) + fulvestrant (FULV) | #1079 poster<br>Breast Cancer – Metastatic<br>Monday 01 June 2026 1:30 - 4:30 PM CDT |
| Kadcyla® (trastuzumab emtansine) | Adjuvant antibody–drug conjugate (ADC) eligibility and corresponding prognosis in HER2+ early breast cancer (eBC): A US-based real-world comparison of KATHERINE and DESTINY-Breast05 populations | #535 poster<br>Breast Cancer – Local/Regional/Adjuvant<br>Monday 01 June 2026 1:30 - 4:30 PM CDT |

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| **Blood cancer** | | |
| Lunsumio® (mosunetuzumab) and Polivy® (polatuzumab vedotin) | Mosunetuzumab plus polatuzumab vedotin (Mosun-Pola) versus rituximab, gemcitabine and oxaliplatin (R-GemOx) in patients with relapsed/refractory large B-cell lymphoma (R/R LBCL): Updated efficacy and safety from the phase 3 SUNMO study including in second-line (2L) versus third-line plus (3L+) patient subgroups | #7007 oral<br>Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia<br>Saturday 30 May 2026<br>5:12 - 5:24 PM CDT |
| Columvi® (glofitamab) | Fixed-duration glofitamab monotherapy in relapsed/refractory (R/R) mantle cell lymphoma (MCL) with/without prior Bruton's tyrosine kinase inhibitor (BTKi) exposure: updated data after a 3.5-year follow-up | #7006 oral<br>Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia<br>Saturday 30 May 2026<br>5:00 - 5:12 PM CDT |
| Polivy | Outcomes by LymphoMAP archetypes in untreated diffuse large B-cell lymphoma from the POLARIX trial | #7017 rapid oral<br>Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia<br>Friday 29 May 2026<br>2:12 - 2:18 PM CDT |
| Columvi, Lunsumio and Polivy | Multivariable analyses (MVAs) of overall survival (OS) in the phase 3 SUNMO, STARGLO and POLARGO trials in relapsed/refractory large B-cell lymphoma (LBCL) | #7093 poster<br>Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia<br>Monday 01 June 2026<br>9:00 - 12:00 PM CDT |
| **Lung cancer** | | |
| Divarasib | First-line (1L) divarasib plus pembrolizumab (pembro) in advanced or metastatic *KRAS* G12C+ non-small cell lung cancer (NSCLC): results from the Krascendo-170 study | #8510 clinical science symposium<br>Lung Cancer — Non-Small Cell Metastatic<br>Saturday 30 May 2026<br>8:36 - 8:48 AM CDT |

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| Tecentriq® (atezolizumab) | Transcriptomic analyses of molecular subsets and correlations with clinical outcomes from the phase 3 IMforte study of lurbinectedin (lurbi) + atezolizumab (atezo) maintenance treatment (Tx) in extensive-stage small-cell lung cancer (ES-SCLC) | #8014 rapid oral<br>Lung Cancer — Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers<br>Sunday 31 May 2026<br>5:12 - 5:18 PM CDT |
| Tecentriq | IMforte: Quality-adjusted time without symptoms or toxicity (Q-TWiST) analysis of first-line maintenance (1Lm) treatment (Tx) with lurbinectedin (lurbi) + atezolizumab (atezo) vs atezo in extensive-stage small cell lung cancer (ES-SCLC) | #8086 poster<br>Lung Cancer — Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers<br>Sunday 31 May 2026<br>9:00 - 12:00 PM CDT |
| **Gastrointestinal cancer** | | |
| Tecentriq | IMbrave251: Final analysis of atezolizumab (atezo) plus lenvatinib (lenva) or sorafenib (sora) vs lenva or sora alone in locally advanced or metastatic hepatocellular carcinoma (LA/mHCC) previously treated with atezo and bevacizumab (bev) | #4002 oral<br>Gastrointestinal Cancer — Gastroesophageal, Pancreatic, and Hepatobiliary<br>Monday 01 June 2026<br>10:09 - 10:21 AM CDT |
| Tecentriq | Health-related quality of life (HRQOL) in the phase 3 trial of standard chemotherapy alone or combined with atezolizumab as adjuvant therapy for patients with stage III deficient DNA mismatch repair (dMMR) colon cancer (Alliance A021502, ATOMIC)* | #3626 poster<br>Gastrointestinal Cancer — Colorectal and Anal<br>Saturday 30 May 2026<br>9:00 - 12:00 PM CDT |
| **Bladder cancer** | | |
| Tecentriq | Patient-reported outcomes from IMvigor011: A phase 3 study of circulating tumor (ct)DNA-guided adjuvant atezolizumab vs placebo in muscle-invasive bladder cancer (MIBC) | #4627 poster<br>Genitourinary Cancer — Kidney and Bladder<br>Sunday 31 May 2026<br>9:00 - 12:00 PM CDT |

*Study led by the Alliance for Clinical Trials in Oncology and supported by Roche

## About Roche in oncology

For over 60 years, Roche has delivered transformative medicines and diagnostics, redefining the treatment of some of the most challenging cancers. Driven by a vision of a future where cancer can be cured, we focus our efforts on cancers with the highest societal impact and where we bring deep expertise, including breast, lung, and blood cancers, while pursuing breakthrough innovation in other areas of unmet need. Our pipeline features a diverse array of modalities, from small molecules and antibodies to next-generation ADCs and allogeneic CAR T-cell therapies. By advancing best-in-class precision medicine, pioneering novel combinations, and leveraging key technologies and partnerships, Roche tackles oncology's toughest challenges with the goal of delivering life-changing outcomes for people with 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.



## References

[1] Kinslow C, et al. Prevalence of Estrogen Receptor Alpha (ESR1) Somatic Mutations in Breast Cancer. JNCI Cancer Spectrum; 2022;6(5):pkac060.
[2] O'Shaughnessy J, et al. Real-world risk of recurrence and treatment outcomes with adjuvant endocrine therapy in patients with stage II-III HR+/HER2- early breast cancer. Breast. 2025;81:104437.
[3] Bardia A, et al. Giredestrant vs standard-of-care endocrine therapy as adjuvant treatment for patients with estrogen receptor-positive, HER2-negative early breast cancer: Results from the global Phase III lidERA Breast Cancer trial. Presented at: San Antonio Breast Cancer Symposium (SABCS); 2025 December 9-12; San Antonio, Texas, United States. #GS1-10.

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