Media & Investor Release

Roche data at ESMO 2025 showcase advances in science and cancer care across multiple tumour types

Basel, 13 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it will present more than 30 abstracts across more than 10 cancer types at the European Society for Medical Oncology (ESMO) Congress 2025, held 17-21 October 2025 in Berlin, Germany. The data underscore Roche's commitment to deliver transformative medicines for some of the most challenging cancer types, including breast cancers, lung cancers, gastrointestinal and genitourinary cancers.

Key presentations include:

- Giredestrant: Primary results from the phase III evERA Breast Cancer study, the first positive head-to-head phase III trial investigating a selective oestrogen receptor (ER) degrader-containing regimen versus a standard of care combination in the post-cyclin-dependent kinase inhibitor setting for people with ER-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer.[1,2] The study met both co-primary endpoints, demonstrating a statistically significant and clinically meaningful improvement in progression-free survival in both the intention-to-treat and *ESR1*-mutated populations.[3] Data will be presented as a late-breaking oral abstract.
- Tecentriq: Results from the IMvigor011 trial, the first global phase III study pioneering a circulating tumour DNA (ctDNA)-guided approach to post-surgery treatment in muscle-invasive bladder cancer (MIBC).[4] Topline results show that people who had detectable ctDNA and were treated with Tecentriq® (atezolizumab) had statistically significant and clinically meaningful improvements in disease-free survival (DFS) and overall survival (OS).[5] Data will be presented as part of the Presidential Symposium.
- Alecensa: Final OS data from the pivotal ALEX study of Alecensa® (alectinib).[6] Alecensa is an established first-line treatment and a standard of care for people with advanced anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).[7-9] Data will be presented as a late-breaking oral abstract and published simultaneously in the *Annals of Oncology*.
- Alecensa: Updated results from the phase III ALINA study, reinforcing the role of adjuvant Alecensa as the standard of care for patients with resected ALK-positive NSCLC.[10] After a median follow-up of approximately four years, Alecensa DFS data compared with chemotherapy will be presented.[10]

Overview of key presentations featuring Roche medicines:

Medicine	Abstract title	Abstract number/presentation details
Breast cancer		
Giredestrant	Giredestrant (GIRE), an oral selective oestrogen receptor (ER) antagonist and degrader, + everolimus (E) in patients (pts) with ER-positive, HER2-negative advanced breast cancer (ER+, HER2– aBC) previously treated with a CDK4/6 inhibitor (i): Primary results of the phase III evERA BC trial	#LBA16 late-breaking oral Proffered paper session 1: Breast cancer, metastatic Saturday 18 October 2025 10:15-10:25 CEST
	Preoperative window-of-opportunity study with giredestrant or tamoxifen (tam) in premenopausal women with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-) and Ki67≥10% early breast cancer (EBC): the EMPRESS study (IIS: MEDSIR)*	#294MO mini oral Mini oral session: Breast cancer, early stage Sunday 19 October 2025 10:50-10:55 CEST
Giredestrant plus Itovebi™ (inavolisib)	Interim analysis of giredestrant (GIRE) + inavolisib (INAVO) in MORPHEUS breast cancer (BC): A phase Ib/II study of GIRE treatment (rx) combinations in patients (pts) with estrogen receptor-positive (ER+), HER2-negative, locally advanced/metastatic BC (LA/mBC)	#508P poster Poster session: Breast cancer, metastatic Monday 20 October 2025 12:00-17:30 CEST
Itovebi™	phase I/Ib trial of inavolisib (INAVO) + pertuzumab (P) + trastuzumab (H) for PIK3CA-mutated (mut), HER2-positive advanced breast cancer (HER2+ aBC)	#548P poster Poster session: Breast cancer, metastatic Monday 20 October 2025 12:00-17:30 CEST
Genitourinary cancer		
Tecentriq® (atezolizumab)	IMvigor011: a phase III trial of circulating tumour (ct)DNA-guided adjuvant	#LBA8 late-breaking oral Presidential Symposium III

Medicine	Abstract title	Abstract number/presentation details
	atezolizumab vs placebo in muscle-invasive bladder cancer	Monday 20 October 2025 16:30-16:42 CEST
Lung cancer		
Alecensa® (alectinib)	Final overall survival (OS) and safety analysis of the phase III ALEX study of alectinib vs crizotinib in patients with previously untreated, advanced ALK-positive (ALK+) non-small cell lung cancer (NSCLC)	#LBA73 late-breaking oral Proffered paper session: NSCLC metastatic Friday 17 October 2025 17:06-17:16 CEST
	Updated results from the phase III ALINA study of adjuvant alectinib vs chemotherapy (chemo) in patients (pts) with early-stage ALK+ non-small cell lung cancer (NSCLC)	#1787MO mini oral Mini oral session 2: Non-metastatic NSCLC Monday 20 October 2025 14:50-14:55 CEST
Tecentriq	Patterns of disease progression (PD) and efficacy associated with tumour burden from the phase III IMforte study of lurbinectedin (lurbi) + atezolizumab (atezo) as first-line (1L) maintenance treatment (tx) in ES-SCLC	#2762MO mini oral Mini Oral session 1: Non-metastatic NSCLC Saturday 18 October 2025 17:15-17:20 CEST
Gastrointestinal cancer		
Tecentriq (IIS: NCI, Alliance)**	Clinical outcome of patients (pts) with sporadic vs Lynch syndrome-related stage III colon carcinoma (CC) with deficient mismatch repair (dMMR) treated in a randomized trial of adjuvant FOLFOX alone or combined with atezolizumab (atezo; anti-PD-L1)	#752P poster Poster session: Colorectal cancer Sunday 19 October 2025
Divarasib	Single-agent divarasib experience in patients with KRAS G12C-positive pancreatic	#927MO mini oral

Medicine	Abstract title	Abstract number/presentation details
	adenocarcinoma (panc), cholangiocarcinoma (cholangio), and other solid tumors	Mini oral session: Developmental therapeutics Friday 17 October 2025 17:00-17:05 CEST

* *Investigator Initiated Study (IIS). The study is sponsored by MEDSIR and supported by Genentech, a member of the Roche Group.*

** *Investigator Initiated Study (IIS). The study is sponsored by the National Cancer Institute (NCI), conducted by the Alliance for Clinical Trials in Oncology and supported by Genentech, a member of the Roche Group.*

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

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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.

References

[1] Mayer E, et al. Giredestrant (GIRE), an oral selective oestrogen receptor (ER) antagonist and degrader, + everolimus (E) in patients (pts) with ER-positive, HER2-negative advanced breast cancer (ER+, HER2– aBC) previously treated with a CDK4/6 inhibitor (i): Primary results of the phase III evERA BC trial. To be presented at: ESMO Congress; 2025 Oct 17-21; Berlin, Germany. Abstract #LBA16.
[2] ClinicalTrials.gov. A Study Evaluating the Efficacy and Safety of Giredestrant Plus Everolimus Compared With the Physician's Choice of Endocrine Therapy Plus Everolimus in Participants With Estrogen Receptor-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer (evERA Breast Cancer) [Internet; cited 2025 October]. Available from: https://clinicaltrials.gov/study/NCT05306340.
[3] Roche. Positive phase III results show Roche's giredestrant significantly improved progression-free survival in ER-positive advanced breast cancer [Internet; cited 2025 October]. Available from: https://www.roche.com/media/releases/med-cor-2025-09-22.
[4] Powles T, et al. IMvigor011: a phase 3 trial of circulating tumour (ct)DNA-guided adjuvant atezolizumab vs placebo in muscle-invasive bladder cancer. To be presented at: ESMO Congress; 2025 Oct 17-21; Berlin, Germany. Abstract #LBA8.
[5] Natera. IMvigor011 Bladder Cancer Trial Achieves Positive Results, with Signatera™ Strongly Predicting Adjuvant Immunotherapy Benefit [Internet; cited 2025 October]. Available from: https://www.natera.com/company/news/imvigor011-bladder-cancer-trial-achieves-positive-results-with-signatera-strongly-predicting-adjuvant-immunotherapy-benefit/https://www.natera.com/company/news/imvigor011-bladder-cancer-trial-achieves-positive-results-with-signatera-strongly-predicting-adjuvant-immunotherapy-benefit/.
[6] Mok T, et al. Final overall survival (OS) and safety analysis of the phase 3 ALEX study of alectinib vs crizotinib in patients with previously untreated, advanced ALK-positive (ALK+) non-small cell lung cancer (NSCLC). To be presented at: ESMO Congress; 2025 Oct 17-21; Berlin, Germany. Abstract #LBA73.
[7] Peters S, et al. Alectinib versus Crizotinib in Untreated ALK-Positive Non-Small-Cell Lung Cancer. N Engl J Med. 2017;377(9); 829-838.
[8] Mok T, et al. Updated overall survival and final progression-free survival data for patients with treatment-naive advanced ALK-positive non-small-cell lung cancer in the ALEX study. Ann Oncol. 2020;31(8):1056-1064.
[9] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer v.5.2024.
[10] Dziadziuszko R, et al. Updated results from the phase III ALINA study of adjuvant alectinib vs chemotherapy (chemo) in patients (pts) with early-stage ALK+ non-small cell lung cancer (NSCLC). To be presented at: ESMO Congress; 2025 Oct 17-21; Berlin, Germany. Abstract #1787MO.

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