Novartis International AG
CH-4002 Basel
Switzerland

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PRESS RELEASE

Novartis to showcase transformative data in advanced prostate and early breast cancer at ESMO 2025

- *Key data from PSMAddition has been selected for a Presidential session; data to showcase the efficacy and safety of Pluvicto™ plus standard of care (SoC) versus SoC alone in PSMA+ mHSPC*
- *NATALEE five-year analysis of Kisqali® to provide further long-term insights into risk of recurrence reduction in a broad EBC patient population*
- *New data for Pluvicto in prostate cancer and Kisqali in breast cancer strengthen the profiles of both medicines, with promise for new SoC in earlier disease settings*

Basel, September 26, 2025 – Novartis will present new data from 34 abstracts across its oncology portfolio at the European Society for Medical Oncology (ESMO) Congress 2025 in Berlin (October 17-21, 2025).

“We look forward to sharing new clinical data that underscores how we are reimagining treatment for breast and prostate cancer, advancing highly effective therapies designed to improve quality of life, enable more personalized care and ultimately provide more time for cancer patients,” said Dushen Chetty, PhD, Global Head of Oncology Development, Novartis, Ad Interim. “Our ambition is to set new standards of care in some of the most prevalent cancers by pioneering novel technologies like radioligand therapy.”

Key highlights of data accepted by ESMO include:

Medicine	**Abstract title**	**Abstract Number/ Presentation Details**
Pluvicto™ (lutetium (^{177}Lu) vipivotide tetraxetan)	Phase 3 trial of [^{177}Lu]Lu-PSMA-617 combined with ADT + ARPI in patients with PSMA-positive metastatic hormone-sensitive prostate cancer (PSMAddition)	#LBA6 Presidential Symposium 2 (Proffered Paper session) October 19, 2025 16:30 – 18:15 CEST
Pluvicto™ (lutetium (^{177}Lu) vipivotide tetraxetan)	Associations between quantitative baseline ^{68}Ga-PSMA-11 PET parameters and ^{177}Lu-PSMA-617 efficacy in the PSMAfore Study	#2390P Poster Presentation October 18, 2025 09:00 – 17:00 CEST
Pluvicto™ (lutetium (^{177}Lu) vipivotide tetraxetan)	Final analysis of patients treated with [^{177}Lu]Lu-PSMA-617 in early access program in metastatic castration-resistant prostate cancer (mCRPC) in France	#2389P Poster Presentation October 18, 2025 09:00 – 17:00 CEST

[^{225}Ac]-PSMA-617	PSMAcTION trial-in-progress: a phase 2/3 randomized trial of [^{225}Ac]Ac-PSMA-617 (^{225}Ac-PSMA-617) versus standard of care in patients with PSMA-positive metastatic castration-resistant prostate cancer who progressed on or after [^{177}Lu]Lu-PSMA therapy	#2516TiP Poster Presentation October 18, 2025 09:00 – 17:00 CEST
Kisqali® (ribociclib)	Adjuvant ribociclib (RIB) plus nonsteroidal aromatase inhibitor (NSAI) in patients (pts) with HR+/HER2− early breast cancer (EBC): NATALEE 5-year outcomes	#LBA14 Proffered Paper session October 17, 2025 14:00 – 15:30 CEST
Kisqali® (ribociclib)	Impact of neoadjuvant chemotherapy (NACT) response on clinical outcomes with ribociclib (RIB) in HR+/HER2− EBC: a subgroup analysis from the phase 3 NATALEE trial	#366P Poster Presentation October 20, 2025 09:00 – 17:00 CEST
Kisqali® (ribociclib)	A NATALEE data–based machine learning (ML) model to predict distant recurrence (DR) and treatment (tx) effect in real-world (RW) patients (pts) with HR+/HER2– early breast cancer (EBC) without CDK4/6 inhibitor (CDK4/6i) tx	#372P Poster Presentation October 20, 2025 09:00 – 17:00 CEST
Kisqali® (ribociclib)	Real-world characteristics, treatments and outcomes of NATALEE and monarchE-eligible HR+/HER2- early breast cancer patients in the hospital district of Helsinki and Uusimaa (HUS), Finland	#360P Poster Presentation October 20, 2025 09:00 – 17:00 CEST
Kisqali® (ribociclib)	Risk of Recurrence (ROR) After Neoadjuvant Ribociclib Plus ET in Clinically High-Risk ER+/HER2− BC: Preliminary Analysis of the SOLTI-RIBOLARIS Trial	#296O Proffered Paper session October 17, 2025 14:00 – 15:30 CEST

Novartis in oncology
The Novartis oncology strategy focuses on people living with cancer and those who care for them, from loved ones to clinical care teams, including their providers. For the past 30+ years, the aim has been to extend and improve lives by discovering differentiated, innovative and practice-changing medicines for patients.

As Novartis reimagines medicine, it collaborates with a wide range of patient advocacy groups and supports education, early cancer screening and diagnosis. With approximately 35 research and development projects across solid tumors, hematology and radioligand therapy (RLT), Novartis is committed to using technology, leading science and patient-centered research to deliver pioneering cancer care for all those in need.

Disclaimer
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“would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people’s lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach nearly 300 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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Novartis Media Relations
E-mail: media.relations@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com