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PRESS RELEASE

New Novartis data at ASCO and EHA showcase momentum of pioneering portfolio with promising pipeline

- *NATALEE subanalysis evaluates Kisqali in pre-menopausal early breast cancer patients, amid rising diagnosis rates in younger patients*
- *Pluvicto analysis and Scemblix ASC4START primary endpoint results provide insights into use in earlier settings*
- *Fabhalta APPULSE-PNH full results build on Phase III program, reporting new data from expanded PNH population in adults switching from anti-C5*
- *Ianalumab Phase II data in immune thrombocytopenia and longer-term pelabresib Phase III data in myelofibrosis show breadth of pipeline in hematologic diseases*

Basel, May 15, 2025 – Novartis will present data from 60 company or investigator sponsored abstracts that have the potential to change clinical practice, at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and the European Hematology Association (EHA) 2025 Congress.

“The breadth of our oncology and hematology portfolio – anchored by Kisqali, Pluvicto, Scemblix and Fabhalta – demonstrates our leadership in both solid tumors and hematologic diseases,” said Shreeram Aradhye, M.D., President, Development and Chief Medical Officer, Novartis. “At ASCO and EHA, we will present new data on these priority medicines as well as updates from our pipeline and our industry-leading radioligand therapy research.”

Novartis will also highlight its US partnerships with the National Football League (NFL), Alliance for Breast Cancer Policy, and ZERO Prostate Cancer, which encourage people to make proactive decisions about their health and advance patient-centered policy solutions to help improve outcomes.

“We're witnessing a profound shift in how people move through their cancer journey, with cancer diagnoses occurring at younger ages and, simultaneously, older patients living longer and approaching aging with new vigor,” said Victor Bultó, President, US, Novartis. “As a leader in driving medical advances in oncology, we have the responsibility to also make a difference in areas beyond treatment innovation. By partnering across the ecosystem, our goal is to advance the conversation around earlier detection and meet the evolving needs of this next generation of cancer patients.”

Key highlights of data accepted by ASCO include:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Kisqali® (ribociclib)*	Efficacy and safety of ribociclib (RIB) + nonsteroidal aromatase inhibitor (NSAI) in NATALEE: Analysis across menopausal status and age	Abstract #516 Rapid Oral June 1, 8:00 – 9:30am CDT
Kisqali® (ribociclib)	Real-world (RW) analysis of characteristics and risk of recurrence (ROR) in Black patients (pts) with HR+/HER2− early breast cancer (EBC) eligible for NATALEE	Abstract #527 Poster Presentation June 2, 9:00am – 12:00pm CDT
Kisqali® (ribociclib)	Adjuvant WIDER: A phase 3b trial of ribociclib (RIB) + endocrine therapy (ET) as adjuvant treatment (tx) in a close-to-clinical-practice patient (pt) population with HR+/HER2− early breast cancer (EBC)	Abstract #TPS617 Poster Presentation June 2, 9:00am – 12:00pm CDT
Kisqali® (ribociclib)	First-line (1L) ribociclib (RIB) + endocrine therapy (ET) vs combination chemotherapy (combo CT) in clinically aggressive hormone receptor (HR)+/HER2− advanced breast cancer (ABC): A subgroup analysis of patients (pts) with or without liver metastases (mets) from RIGHT Choice	Abstract #1069 Poster Presentation June 2, 9:00am – 12:00pm CDT
Scemblix® (asciminib)	Efficacy and safety of asciminib (ASC) in patients (pts) with chronic-phase chronic myeloid leukemia (CML-CP) after 1 tyrosine kinase inhibitor (TKI): Interim analysis (IA) of the phase 2 ASC2ESCALATE trial	Abstract #6516 Rapid Oral May 30, 1:00 – 2:30pm CDT
Scemblix® (asciminib)	Primary endpoint results of the phase 3b ASC4START trial of asciminib (ASC) vs nilotinib (NIL) in newly diagnosed chronic phase chronic myeloid leukemia (CML-CP): Time to treatment discontinuation due to adverse events (TTDAE)	Abstract #6501 Oral Presentation June 2, 3:00 – 6:00pm CDT
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Clinical outcomes of prompt versus deferred 177Lu-PSMA-617 initiation for metastatic castration-resistant prostate cancer (mCRPC) based on prior androgen receptor pathway inhibitor (ARPI) and taxane chemotherapy exposure: a real-world PRostatE Cancer dISease observatION (PRECISION) data platform analysis	Abstract #e17030 Online Publication
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Real-world outcomes among patients with metastatic castration-resistant prostate cancer (mCRPC) receiving guideline-recommended therapies after treatment with 177Lu-PSMA-617: a real-world	Abstract #e17035 Online Publication

	PRostatE Cancer dISease observatION (PRECISION) data platform analysis	
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	PSMA-delay castration (DC): An open-label, multicenter, randomized phase 3 study of [177Lu]Lu-PSMA-617 versus observation in patients with metachronous PSMA-positive oligometastatic prostate cancer (OMPC)	Abstract #TPS5127 Poster Presentation June 2, 9:00am – 12:00pm CDT

Key highlights of data accepted by EHA include:

Medicine	**Abstract Title**	**Abstract Number/ Presentation Details**
Fabhalta® (iptacopan)	APPULSE-PNH: Oral iptacopan monotherapy demonstrates clinically meaningful hemoglobin (Hb) increases in patients (pts) with paroxysmal nocturnal hemoglobinuria (PNH) and Hb ≥10 g/dL on anti-C5 therapy	Abstract #S183 Oral Presentation June 13, 5:00 – 6:15pm CEST
Fabhalta® (iptacopan)	The 2-year safety and efficacy of iptacopan monotherapy in patients with paroxysmal nocturnal hemoglobinuria (PNH) from APPLY- and APPOINT-PNH studies who entered the roll-over extension program (REP)	Abstract #PF660 Poster Presentation June 13, 6:30 – 7:30pm CEST
Scemblix® (asciminib)	Asciminib (ASC) shows superior tolerability vs nilotinib (NIL) in newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP): Primary endpoint results of the phase (Ph) 3b ASC4START trial	Abstract #S166 Oral Presentation June 13, 5:00 – 6:25pm CEST
Scemblix® (asciminib)	Improved patient-reported outcomes (PROs) with asciminib (ASC) vs investigator-selected tyrosine kinase inhibitors (IS-TKIs) in newly diagnosed chronic myeloid leukemia (CML): ASC4FIRST wk 48 analysis	Abstract #PS1588 Poster Presentation June 14, 6:30 – 7:30pm CEST
Scemblix® (asciminib)	Interim analysis (IA) results from ASC2ESCALATE support asciminib (ASC) as a treatment (Tx) option in chronic-phase chronic myeloid leukemia (CML-CP) after 1 tyrosine kinase inhibitor (TKI)	Abstract #PF595 Poster Presentation June 13, 6:30 – 7:30pm CEST
Pelabresib (DAK539)	Pelabresib in combination with ruxolitinib for janus kinase inhibitor-naive patients with myelofibrosis: 72-week follow-up with long-term efficacy outcomes of the phase III MANIFEST-2 study	Abstract #S223 Oral Presentation June 12, 5:00 – 6:15pm CEST
Ianalumab (VAY736)	A Phase 2 Study of Ianalumab in patients with primary immune thrombocytopenia	Abstract #S312 Oral Presentation June 15, 11:00am – 12:15pm CEST

	previously treated with at least two lines of therapy (VAYHIT3)	
Rapcabtagene autoleucel (YTB323)	Rapcabtagene Autoleucel (YTB323) in patients with relapsed/refractory diffuse large B-cell lymphoma: A phase II trial clinical update	Abstract #PF1152 Poster Presentation June 13, 6:30 – 7:30pm 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, all while innovating at a rate that is unparalleled in the industry. 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

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “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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*Kisqali was developed by Novartis under a research collaboration with Astex Pharmaceuticals.

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