

MEDIA & INVESTOR RELEASE

Novartis highlights new 96-week results from Phase III Scemblix® ASC4FIRST trial at ASH and late-breaking analysis from Phase III Kisqali® NATALEE trial at SABCS

- *Longer-term 96-week results from Scemblix® ASC4FIRST Phase III study in first-line Ph+ CML-CP to be presented following recent FDA approval based on 48-week data*
- *Late-breaking Kisqali®* 4-year analysis on distant disease-free survival in key subgroups with HR+/HER2- early breast cancer from Phase III NATALEE trial also to be presented*
- *Pipeline updates demonstrate advancement in research and development programs in hematologic diseases and cancers*

Basel, November 25, 2024 – Novartis will present data from more than 65 abstracts, including investigator-initiated trials at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition and the 2024 San Antonio Breast Cancer Symposium® (SABCS).

“By prioritizing research in areas of greatest medical need and focusing on earlier stages of disease, we aim to change the treatment paradigm for people who require additional treatment options,” said Jeff Legos, Executive Vice President, Global Head of Oncology Development, Novartis. “The new data being presented at ASH and SABCS underscore our commitment to patients with cancer or blood disorders and follow new, expanded indications for Scemblix and Kisqali along with recent updates in national treatment guidelines.”

In addition to late-breaking data, Novartis will host an art gallery-style exhibit at SABCS featuring personal letters and stories written by people impacted by breast cancer, sharing their raw, authentic perspectives on aspects of the breast cancer journey. These letters and stories aim to uplift patients, encourage reflection, and demonstrate strength and unity among the breast cancer community.

Key abstracts accepted by ASH include:

Medicine or Disease State	Abstract Title	Abstract Number/ Presentation Details
Scemblix®	Asciminib (ASC) Demonstrates Favorable Safety and Tolerability Compared with Each Investigator-	Abstract #475 Oral Presentation Sunday, December 8

	Selected Tyrosine Kinase Inhibitor (IS TKI) in Newly Diagnosed Chronic Myeloid Leukemia in Chronic Phase (CML-CP) in the Pivotal Phase 3 ASC4FIRST Study	9:30 – 11:00 AM PT
Scemblix	Efficacy and Safety of Asciminib in Chronic Myeloid Leukemia in Chronic Phase (CML-CP): Interim Results from the Phase 2 ASC2ESCALATE Trial in the Cohort of Patients (Pts) after 1 Prior Tyrosine Kinase Inhibitor (TKI)	Abstract #479 Oral Presentation Sunday, December 8 9:30 – 11:00 AM PT
Scemblix	Asciminib Shows High Efficacy and Favorable Tolerability at 80 Mg Once Daily and 40 Mg Twice Daily in Patients with Chronic Phase Chronic Myelogenous Leukemia Previously Treated with 2 or More Tyrosine Kinase Inhibitors: Primary Analysis from the ASC4OPT Study	Abstract #4526 Poster Presentation Monday, December 8 6:00 – 8:00 PM PT
Scemblix	Treatment with Asciminib as a Second Line after One Prior Tyrosine Kinase Inhibitor (TKI) in Patients with Chronic-Phase Chronic Myeloid Leukemia (CML-CP)– a Chart Review Study in the United States	Abstract #3812 Poster Presentation Sunday, December 8 6:00 – 8:00 PM PT
Ianalumab (VAY736)	A Phase 2 Study of Ianalumab in Patients with Primary Immune Thrombocytopenia Previously Treated with at Least Two Lines of Therapy: Interim Results from VAYHIT3	Abstract #710 Oral Presentation Monday, December 9 10:30 AM – 12:00 PM PT
Rapcabtagene autoleucel (YTB323)	Rapcabtagene Autoleucel (YTB323) in Patients (Pts) with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL): Phase II Trial Clinical Update	Abstract #67 Oral Presentation Saturday, December 7 9:30 – 11:00 AM PT
Fabhalta®	Oral Iptacopan Monotherapy Leads to Long-Term Improvements in Patient (Pt)-Reported Health-Related Quality of Life (HRQoL) and Investigator-Assessed Signs and Symptoms of Paroxysmal Nocturnal Hemoglobinuria (PNH): 48-Week (Wk) Results from the Phase III APPLY-PNH and APPOINT-PNH Trials	Abstract #4079 Poster Presentation Monday, December 9 6:00 – 8:00 PM PT
Fabhalta	The Effect of Oral Iptacopan Monotherapy on Hematological Parameters in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Is Consistent Regardless of the Type of Prior Anti-C5 Treatment Received: A Post Hoc Analysis of 24-Week Data from the Randomized Phase III APPLY-PNH Trial	Abstract #4087 Poster Presentation Monday, December 9 6:00 – 8:00 PM PT

Fabhalta	Baseline Characteristics of Individuals with Paroxysmal Nocturnal Hemoglobinuria in an App-Based Home-Reported Outcomes Study to Evaluate Disease Burden	Abstract #2327 Poster Presentation Saturday, December 7 5:30 – 7:30 PM PT
Pelabresib (CPI-0610)	Updated Results from the Phase 3 Manifest-2 Study of Pelabresib in Combination with Ruxolitinib for Janus Kinase Inhibitor–Naïve Patients with Myelofibrosis	Abstract #3178 Poster Presentation Sunday, December 8 6:00 PM - 8:00 PM PT

Key abstracts accepted by SABCS include:

Medicine or Disease State	Abstract Title	Abstract Number/ Presentation Details
Kisqali® (ribociclib)*	Distant disease-free survival (DDFS) across key subgroups from the phase 3 NATALEE trial of ribociclib (RIB) plus a nonsteroidal aromatase inhibitor (NSAI) in patients with HR+/HER2- early breast cancer (EBC)	Abstract #P4-09-22 Poster Session Thursday, December 12 5:30 – 7:30 PM CST
Kisqali	Impact of ribociclib dose reduction on efficacy in patients with hormone receptor– positive/human epidermal growth factor receptor 2–negative (HR+/HER2-) early breast cancer (EBC) in NATALEE	Abstract #P1-11-16 Poster Session Wednesday, December 11 12:30 – 2:00 PM CST
Kisqali	Risk of recurrence in real-world (RW) NATALEE- and monarchE-eligible populations of patients with HR+/HER2- early breast cancer (EBC) in an electronic health record (EHR)-derived database	Abstract #P2-12-02 Poster Session Wednesday, December 11 5:30 – 7:00 PM CST
Kisqali	Tolerability of First-Line (1L) Treatment (tx) With Ribociclib (RIB) for Metastatic Breast Cancer (MBC) Using 2 Large US Data Sources	Abstract #P3-10-14 Poster Session Thursday, December 12 12:30 – 2:00 PM CST
Kisqali	Impact of body mass index (BMI) on the safety and efficacy of ribociclib (RIB) in patients (pts) with HR+/HER2- advanced breast cancer (ABC): pooled analysis of the MONALEESA (ML)-2, -3, and -7 trials	Abstract #P2-09-20 Poster Session Wednesday, December 11 5:30 – 7:00 PM CST
Kisqali	First-line (1L) ribociclib (RIB) + endocrine therapy (ET) vs combination chemotherapy (combo CT) in clinically aggressive HR+/HER2- advanced breast cancer (ABC): a subgroup analysis of RIGHT Choice by intrinsic subtype & gene & signature expression	Abstract #PS2-06 Poster Presentation Thursday, December 12 7:00 – 8:30 AM CST

Product Information

For full prescribing information, including approved indications and important safety information about marketed products, please visit <https://www.novartis.com/about/products>.

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 more than 250 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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