

MEDIA & INVESTOR RELEASE

Novartis showcases significant data updates from Kisqali[®], iptacopan and Scemblix[®] at SABCS and ASH

- *Late-breaking final iDFS analysis from NATALEE investigating Kisqali[®] (ribociclib) in broad population of patients with stage II and III HR+/HER2- early breast cancer, including those with node-negative disease*
- *New 48-week efficacy and safety data from the Phase III APPLY-PNH trial of investigational oral monotherapy iptacopan in anti-C5-treated adult patients with paroxysmal nocturnal hemoglobinuria (PNH) and persistent anemia*
- *Nearly 4 year follow-up efficacy and safety results from end of study treatment update of ASCSEMBL with Scemblix[®] (asciminib) in patients with Ph+ chronic phase-chronic myeloid leukemia (CP-CML) after ≥2 Prior Tyrosine Kinase Inhibitors*

Basel, November 20, 2023 — Novartis will present data from over 100 trials across its breast cancer and hematology portfolios at the 2023 San Antonio Breast Cancer Symposium (SABCS) and the American Society of Hematology (ASH) Annual Meeting & Exposition. The new data will highlight the latest advances across our breast cancer and hematology portfolios and pipeline, such as the Phase III NATALEE trial and Phase III APPLY-PNH trial.

“We’re developing new therapies across a range of cancers and blood disorders as well as evaluating the potential of our priority medicines in earlier stages of disease,” said Jeff Legos, Executive Vice President, Global Head of Oncology Development at Novartis. “Among the new findings we will present at SABCS and ASH this year are additional follow-up Kisqali data from NATALEE, adding to the body of evidence of ribociclib in early breast cancer, as well as new 48-week data from the Phase III APPLY-PNH trial for iptacopan.”

Key highlights of data accepted by SABCS include:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Kisqali [®] (ribociclib)*	Ribociclib (RIB) + nonsteroidal aromatase inhibitor (NSAI) as adjuvant treatment in patients with HR+/HER2- early breast cancer: final invasive disease-free survival (iDFS) analysis from the NATALEE trial	Abstract #GS03-03 Oral Presentation Friday, December 8 8:15 – 11:15 AM CT

Kisqali® (ribociclib)*	Invasive disease-free survival as a surrogate for overall survival in patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative early breast cancer: a real-world analysis	Abstract #PO1-17-07 Poster Session Wednesday, December 6 12:00 – 2:00 PM CT
Kisqali® (ribociclib)*	Patient preferences for CDK4/6 inhibitor treatments in HR+/HER2- early breast cancer: a discrete choice survey study	Abstract #PO2-01-09 Poster Session Wednesday, December 6 5:00 – 7:00 PM CT

Key highlights of data accepted by ASH include:

Medicine or Disease State	Abstract Title	Abstract Number/ Presentation Details
Iptacopan (LNP023)	Factor B Inhibition with Oral Iptacopan Monotherapy Demonstrates Sustained Long-Term Efficacy and Safety in Anti-C5-Treated Patients (pts) with Paroxysmal Nocturnal Hemoglobinuria (PNH) and Persistent Anemia: Final 48-Week Results from the Multicenter, Phase III APPLY-PNH Trial	Abstract #571 Oral Presentation Sunday, December 10 4:30 PM PT
Iptacopan (LNP023)	Patient-Reported Improvements in Fatigue and Health-Related Quality of Life in the Phase 3 Studies APPLY-PNH and APPOINT-PNH Evaluating the Use of Iptacopan in C5 Inhibitor-Treated and Treatment-Naïve Patients with Paroxysmal Nocturnal Hemoglobinuria	Abstract #487 Oral Presentation Sunday, December 10 9:30 AM PT
Iptacopan (LNP023)	Categorization of Hematological Responses to Oral Iptacopan Monotherapy in Anti-C5-Treated Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) and Persistent Anemia in the Phase III APPLY-PNH Trial and Complement Inhibitor-Naïve Patients in the Phase III APPOINT-PNH Trial	Abstract #4084 Poster Presentation Monday, December 11 6:00 – 8:00 PM PT
Iptacopan (LNP023)	Clinical Breakthrough Hemolysis (BTH) during Monotherapy with the Oral Factor B Inhibitor Iptacopan Is Generally Not Severe and Managed without Treatment Discontinuation: 48-Week Data from the Phase III APPLY-PNH and APPOINT-PNH Trials in Paroxysmal Nocturnal Hemoglobinuria (PNH)	Abstract #1338 Poster Presentation Saturday, December 9 5:30 – 7:30 PM PT
Scemblix® (asciminib)	Sustained Efficacy and Safety with Asciminib (ASC) after Almost 4 Years of Median Follow-up from ASCSEMBL, a Phase 3 Study of ASC vs Bosutinib	Abstract #4536 Poster Presentation Monday, December 11 6:00 – 8:00 PM PT

	(BOS) in Patients (Pts) with Chronic Myeloid Leukemia in Chronic Phase (CML-CP) after ≥2 Prior Tyrosine Kinase Inhibitors (TKIs): An End of Study Treatment (EOS Tx) Update, Including Results from Switch Population	
Scemblix® (asciminib)	With up to 8 Years of Therapy, Asciminib (ASC) Monotherapy Demonstrated Continued Favorable Efficacy, Safety, and Tolerability in Patients (Pts) with Philadelphia Chromosome–Positive Chronic Myeloid Leukemia in Chronic Phase (Ph+ CML-CP) without the T315I Mutation: Final Results from the Phase 1 X2101 Study	Abstract #450 Oral Presentation Sunday, December 10 10:45 AM PT
Sickle Cell Disease	Targeted Degradation of the Wiz Transcription Factor for Gamma Globin De-Repression	Abstract #2 Plenary Scientific Session Sunday, December 10 2:00 – 4:00 PM PT
Kymriah® (tisagenlecleucel)	Clinical Outcomes of Patients with Relapsed/Refractory Follicular Lymphoma Treated with Tisagenlecleucel: Phase 2 Elara 3-Year Follow-up	Abstract #601 Oral Presentation Sunday, December 10 4:30 PM PT
Jakavi® (ruxolitinib)	Ruxolitinib in Patients With Chronic Graft-Versus-Host Disease: 3-Year Final Analysis of Efficacy and Safety From the Phase III REACH3 study	Abstract #654 Oral Presentation Sunday, December 10 5:45 PM PT
Immune Thrombocytopenia (ITP)	The lack of tolerable treatment options that can induce durable responses without fear of relapse after discontinuation represents a significant unmet need for patients (pts) with immune thrombocytopenia (ITP): Results from the ITP world impact survey (I-WISH) 2.0	Abstract #1212 Poster Presentation Saturday, December 9 5:30 – 7:30 PM PT

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,” “seek,” “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](#).

#

* Kisqali was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

Novartis Media Relations

E-mail: media.relations@novartis.com

Central

Richard Jarvis +41 79 584 2326
Anja von Treskow +41 79 392 9697
Anna Schäfers +41 79 801 7267

North America

Julie Masow +1 862 579 8456
Michael Meo +1 862 274 5414
Marlena Abdinoor +1 617 335 9525

Switzerland

Satoshi Sugimoto +41 79 619 2035

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central

Samir Shah +41 61 324 7944
Nicole Zinsli-Somm +41 61 324 3809
Isabella Zinck +41 61 324 7188
Imke Kappes +41 61 324 82 69
Zain Iqbal +41 61 324 03 90

North America

Sloan Simpson +1 862 345 4440
Parag Mahanti +1 973 876 4912
Jonathan Graham +1 201 602 9921