

Novartis highlights pioneering innovation in CML with data from Scemblix® Phase III ASC4FIRST study in newly diagnosed patients at ASCO and EHA

May 15, 2024

- *Primary results of the Scemblix® ASC4FIRST pivotal Phase III study in first-line Ph+ CML-CP supporting third US FDA Breakthrough Therapy designation, to be detailed in the ASCO Press Program and the EHA Plenary Session*
- *Latest data from the Kisqali®* NATALEE trial, including efficacy endpoints for patients with node-negative stage II and III HR+/HER2- early breast cancer*
- *New radioligand therapy portfolio data supporting overall platform leadership and ongoing expansion in research infrastructure and supply capabilities*

East Hanover, May 15, 2024 – Novartis will present data from more than 60 abstracts, including investigator-initiated trials at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and the European Hematology Association (EHA) 2024 Hybrid Congress. The primary results from ASC4FIRST, a pivotal Phase III study of Scemblix® (asciminib) versus standard of care tyrosine kinase inhibitors (imatinib, nilotinib, dasatinib, and bosutinib) in newly diagnosed patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) will be shared at the ASCO official Press Program and at the EHA Plenary Session.

“Despite progress, people with CML continue to struggle to find treatment that is both efficacious and tolerable for them at diagnosis and beyond. We look forward to sharing the primary analysis from the pivotal Phase III ASC4FIRST trial, which builds on our over 20-year legacy to transform care for people diagnosed with CML,” said Jeff Legos, Executive Vice President, Global Head of Oncology, Novartis. “With these promising data, a new analysis of the NATALEE trial in patients with node-negative early breast cancer and additional updates from our RLT portfolio, we further our efforts to reimagine medicine for those with cancer in partnership with the scientific community.”

Key highlights of data accepted by ASCO include:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Scemblix	ASC4FIRST, a pivotal phase 3 study of asciminib (ASC) vs investigator-selected tyrosine kinase inhibitors (IS TKIs) in newly diagnosed patients (pts) with chronic	Abstract #LBA6500 Oral presentation Friday, May

myeloid leukemia (CML): Primary results

31

2:45 - 5:45pm
CDT

Abstract #512

Kisqali®
(ribociclib)

Baseline (BL) characteristics and efficacy endpoints for patients (pts) with node-negative (N0) HR+/HER2- early breast cancer (EBC): NATALEE trial

Rapid oral
presentation

Friday, May
31

2:45 - 4:15pm
CDT

Abstract
#1012

Kisqali

On-treatment (tx) dynamic circulating tumor DNA changes (Δ ctDNA) associated with progression-free survival (PFS) and overall survival (OS) of patients (pts) with HR+/HER2- advanced breast cancer (ABC) in MONALEESA-3 (ML-3)

Clinical
Science
Symposium

Sunday, June
2

4:30 - 6:00pm
CDT

Abstract #541

Kisqali

Short-term risk of recurrence in patients (pts) with HR+/HER2- early breast cancer (EBC) treated with endocrine therapy (ET) in randomized clinical trials (RCTs): A meta-analysis

Poster
presentation

Sunday, June
2

9:00am -
12:00pm CDT

Kisqali

Real-world (RW) risk recurrence among patients (pts) diagnosed with stage II-III HR+/HER2- early breast cancer (EBC) treated with endocrine therapy (ET) in the US

Abstract
#e12533

Online
publication

Abstract
#5003

Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Health-related quality of life and pain in a phase 3 study of [¹⁷⁷ Lu]Lu-PSMA-617 in taxane-naïve patients with metastatic castration-resistant prostate cancer (PSMAfore)	Oral presentation Saturday, June 1 3:00 - 6:00pm CDT Abstract #5008
Pluvicto	Baseline ctDNA analyses and associations with outcomes in taxane-naïve patients with mCRPC treated with ¹⁷⁷ Lu-PSMA-617 versus change of ARPI in PSMAfore	Oral presentation Saturday, June 1 3:00 - 6:00pm CDT
Pluvicto	Real-world clinical outcomes and economic burden of early discontinuation of taxane therapy among patients with metastatic castration-resistant prostate cancer	Abstract #e17043 Online publication
Pluvicto	Patient characteristics, treatment patterns and early trends of lutetium Lu 177 vipivotide tetraxetan (¹⁷⁷ Lu-PSMA-617) use by US urologists and oncologists	Abstract #e17048 Online publication
Lutathera® (lutetium Lu 177 dotatate)	Safety and time to response of [¹⁷⁷ Lu]Lu-DOTATATE in patients with newly diagnosed advanced grade 2 and grade 3, well-differentiated gastroenteropancreatic neuroendocrine tumors: Sub-analysis of the phase 3 randomized NETTER-2 study	Abstract #4131 Poster presentation Saturday, June 1 1:30 - 4:30pm CDT

At the ASCO Annual Meeting, Novartis will also address health equity at the company's booth on the meeting floor, with the *More Than Just Words* virtual reality experience. Meeting attendees will have the opportunity to immerse themselves in scenarios inspired by real-life microaggressions Black patients face due to bias in care, and explore resources co-created with leading multidisciplinary experts to help foster productive, nonbiased conversations about breast cancer risk, diagnosis, and care.

Key highlights of data accepted by EHA include:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Scemblix	Asciminib (ASC) provides superior efficacy and excellent safety and tolerability vs tyrosine kinase inhibitors (TKI) in newly diagnosed chronic myeloid leukemia (CML) in the pivotal ASC4FIRST study	Abstract #S103 Plenary oral presentation Saturday, June 15 2:45 - 4:15pm CEST
Scemblix	Asciminib (ASC) is well tolerated in pediatric patients with chronic myeloid leukemia in chronic phase (CML-CP): interim pharmacokinetics and safety results from ASC4KIDS	Abstract #P1865 e-Poster presentation
Fabhalta [®] (iptacopan)	Effects of oral iptacopan monotherapy, including increased paroxysmal nocturnal hemoglobinuria red blood cell clone size, are sustained in anti-c5-treated patients with anemia: final APPLY-PNH data	Abstract #P829 Poster presentation Friday, June 14 9:00am CEST
Fabhalta	Effects of oral iptacopan monotherapy, including increased paroxysmal nocturnal hemoglobinuria red blood cell clone size, are maintained in complement inhibitor-naïve patients: final APPOINT-PNH data	Abstract #P822 Poster presentation Friday, June 14 9:00am CEST

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 <https://www.novartis.us> and connect with us on [LinkedIn](#), [LinkedIn US](#), [Facebook](#), [X/Twitter](#), [X/Twitter US](#) and [Instagram](#).

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

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Source URL: <https://qa1.novartis.us/news/media-releases/novartis-highlights-pioneering-innovation-cml-data-from-scemblix-phase-iii-asc4first-study-newly-diagnosed-patients-asco-and-eha>

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