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
Kisqali® (ribociclib)	Baseline (BL) characteristics and efficacy endpoints for patients (pts) with node-negative (N0) HR+/HER2– early breast cancer (EBC): NATALEE trial	Abstract #512 Rapid oral presentation Friday, May 31 2:45 - 4:15pm CDT
Kisqali	On-treatment (tx) dynamic circulating tumor DNA changes (ΔctDNA) 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)	Abstract #1012 Clinical Science Symposium Sunday, June 2 4:30 - 6:00pm CDT
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	Abstract #541 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
Pluvicto	Baseline ctDNA analyses and associations with outcomes in taxane-naive patients with mCRPC treated with ^{177}Lu-PSMA-617 versus change of ARPI in PSMAfore	Abstract #5008 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

Fabhalta	Patient experience of iptacopan in three clinical trials for paroxysmal nocturnal hemoglobinuria	Abstract #P1918 e-Poster presentation

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

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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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