Novartis highlights scientific advances with Kisqali, iptacopan, Scemblix and YTB323 data at SABCS and ASH

Nov 22, 2022

- First data to be presented as a late-breaker abstract from global pivotal APPLY-PNH trial of investigational oral monotherapy iptacopan in paroxysmal nocturnal hemoglobinaria (PNH), a rare and serious complement-mediated blood disorder
- New data evaluating the superiority of first-line (1L) Kisqali® plus endocrine therapy vs. combination chemotherapy in pre-menopausal patients with HR+/HER2- metastatic breast cancer with aggressive disease, including patients with visceral disease
- New analysis from Scemblix® ASCEMBL trial on factors of response in pre-treated patients with Ph+ CML-CP and trial-in-progress update from ASC4FIRST, investigating Scemblix in newly diagnosed patients
- New follow-up data from the ongoing Phase I trial with our next generation CAR-T cell therapy rapcabtagene autoleucel (YTB323) in r/r DLBCL using the Novartis-developed T-Charge™ platform

EAST HANOVER, N.J., Nov. 22, 2022 -- Novartis will present data on the latest advancements in breast cancer and hematology at the 2022 San Antonio Breast Cancer Symposium (SABCS), December 6-10, and the American Society of Hematology (ASH) Annual Meeting, December 10-13. More than 130 abstracts, from both Novartis-sponsored trials and investigator-initiated trials using Novartis compounds, were accepted at the meetings, reinforcing Novartis leadership and innovation in priority oncology therapeutic areas.

"Novartis continues to pioneer critical medicines that redefine treatment goals in cancer and non-malignant hematology," said Jeff Legos, Executive Vice President, Global Head of Oncology & Hematology Development, Novartis. "At SABCS and ASH this year, we'll share new clinically-relevant and patient-focused data for Kisqali in aggressive metastatic breast cancer, and for Scemblix and YTB323 in life-threatening blood cancers, and potentially practice-changing data for iptacopan in PNH, underscoring the strength of our promising pipeline."

Key highlights of data accepted by SABCS:

Medicine	Abstract Title	Abstract Number/ Presentation Details
		Abstract

		#GS1-10
Kisqali® (ribociclib)*	Primary results from the randomized Phase II RIGHT Choice trial of premenopausal patients with aggressive HR+/HER2– advanced breast cancer treated with ribociclib + endocrine therapy vs physician's choice combination chemotherapy	Oral Presentation Tuesday, December 6 5:15 PM ET
Kisqali® (ribociclib)*	Pooled analysis of post-progression treatments after first-line ribociclib + endocrine therapy in patients with HR+/HER2- advanced breast cancer in the MONALEESA-2, -3, and -7 studies	Abstract #P4-01-42 Poster Presentation Thursday, December 8 8:00 AM ET
Kisqali® (ribociclib)*	Pooled gene expression analysis and association with treatment response in patients with HR+/HER2– advanced breast cancer in the MONALEESA-2, -3, and -7 trials	Abstract #PD17-08 Poster Discussion Friday, December 9 8:00 AM ET
Piqray® (alpelisib)	Long-term and very-long-term disease control in patients from BYLieve study cohort A with PIK3CA-Mutant, hormone receptor-positive, human epidermal growth factor receptor 2-negative, advanced breast cancer	Abstract #PD13-06 Poster Discussion Thursday, December 8 6:00 PM ET
		Abstract #PD8-02

Piqray® (alpelisib)	Metformin (MET) for the prevention of alpelisib (ALP)-related hyperglycemia (HG) in PIK3CA-mutated, hormone receptor-positive (HR[+]) HER2-negative (HER2[-]) advanced breast cancer (ABC): The METALLICA study†	Poster Discussion Wednesday, December 7 6:00 PM ET

Key highlights of data accepted by ASH:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Iptacopan (LNP023)	Oral monotherapy with iptacopan, a proximal complement inhibitor of factor B, has superior efficacy to intravenous terminal complement inhibition with standard of care Eculizumab or Ravulizumab and favorable safety in patients with paroxysmal nocturnal hemoglobinuria and residual anemia: Results from the randomized, active-comparator-controlled, open-label, multicenter, Phase III APPLY-PNH study	Abstract #LBA-2 Oral Presentation Tuesday, December 13 9:15 AM ET
Iptacopan (LNP023)	Dose–exposure–response relationships of biomarkers and efficacy measures with iptacopan, a complement factor B inhibitor, in patients (pts) with paroxysmal nocturnal hemoglobinuria (PNH) with or without concomitant anti-C5 therapy	Abstract #2571 Poster Presentation Sunday, December 11 6:00 – 8:00 PM ET
Scemblix® (asciminib)	Efficacy and safety results from ASC4MORE, a randomized study of asciminib (ASC) add-on to imatinib (IMA), continued IMA, or switch to nilotinib (NIL) in patients (pts) with chronic-phase chronic myeloid leukemia	Abstract #80 Oral Presentation Saturday,

	(CML-CP) not achieving deep molecular responses (DMRs) with ≥1 year of IMA	December 10 9:45 AM ET
Scemblix® (asciminib)	Dynamics of response and response factors in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) after ≥2 prior tyrosine kinase inhibitors (TKIs) in the phase 3 ascembl study	Abstract #3008 Poster Presentation Sunday, December 11 6:00 PM - 8:00 PM ET
Scemblix® (asciminib)	ASC4FIRST: A Phase III study of asciminib vs investigator-selected tyrosine kinase inhibitor in patients with newly diagnosed chronic myeloid leukemia in chronic phase (CML-CP)	Abstract #3012 Poster Presentation Sunday, December 11 6:00 PM - 8:00 PM ET
Scemblix® (asciminib)	ASC4START: A Phase IIIb, open-label, randomized study of tolerability and efficacy of asciminib versus nilotinib in patients with newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase	Abstract #3021 Poster Presentation Sunday, December 11 6:00 PM – 8:00 PM ET
		Abstract

		#608
Kymriah® (tisagenlecleucel)	Long-term clinical outcomes and correlative efficacy analyses in patients (pts) with relapsed/refractory follicular lymphoma (r/r FL) treated with tisagenlecleucel in the ELARA trial	Oral Presentation Sunday, December 11 4:45 PM ET Abstract #656
Kymriah® (tisagenlecleucel)	Real-world outcomes for patients with relapsed or refractory (r/r) aggressive B-cell non-Hodgkin's lymphoma (aBNHL) treated with commercial tisagenlecleucel: subgroup analyses from the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry	Oral Presentation Sunday, December 11 4:45 PM ET
YTB323 (rapcabtagene autoleucel)	YTB323 (rapcabtagene autoleucel) demonstrates durable efficacy and a manageable safety profile in patients with relapsed/refractory diffuse large B-cell lymphoma (r/r DLBCL): Phase I study update	Abstract #439 Oral Presentation Sunday, December 11 9:30 AM ET
Jakavi® (ruxolitinib)	Ruxolitinib in pediatric patients with treatment-naive or steroid refractory acute graft versus host disease: Primary findings from the Phase I/II REACH4 study	Abstract #572 Oral Presentation Sunday, December 11 12:15 PM ET

Sabatolimab (MBG453)	Primary results of STIMULUS-MDS1: A randomized, double-blind, placebo-controlled Phase II study of TIM-3 inhibition with sabatolimab added to hypomethylating agents (hmas) in adult patients with higher-risk myelodysplastic syndromes (MDS)	Abstract #853 Oral Presentation Monday, December 12 2:45 PM ET
Sabatolimab (MBG453)	Disease characteristics and International Prognostic Scoring Systems (IPSS, IPSS-R, IPSS-M) in adult patients with higher-risk myelodysplastic syndromes (MDS) participating in two randomized, double-blind, placebo-controlled studies with intravenous sabatolimab added to hypomethylating agents (HMA) (STIMULUS-MDS1 and MDS2)	Abstract #559 Oral Presentation Sunday, December 11 12:00 PM ET

Product Information

Approved indications for products vary by country and not all indications are available in every country. The product safety and efficacy profiles have not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that compounds will become commercially available with additional indications.

For full prescribing information, including approved indications and important safety information about marketed products, please visit https://www.novartisoncology.com/news/product-portfolio.

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 such as COVID-19; 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
Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of Novartis – is reimagining medicine to improve and extend people's lives. We deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis employs nearly 14,500 people in the United States. For more information, please visit https://www.novartis.us

Novartis and Novartis US is on Twitter. Sign up to follow @Novartis at https://twitter.com/novartisnews and @NovartisUS at https://twitter.com/NovartisUS.

For Novartis multimedia content, please visit https://www.novartis.com/news/media-library.

For questions about the site or required registration, please contact media.relations@novartis.com.

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

# # #

Novartis Media Relations

E-mail: media.relations@novartis.com

North America

Julie Masow +1 862 579 8456

Michael Meo +1 862 274 5414

Mary Carmichael +1 862 200 8344

Novartis Investor Relations

E-mail: investor.relations@novartis.com

North America

Sloan Simpson +1 862 778 5052
