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# **MEDIA & INVESTOR RELEASE**

# Novartis to present new data across oncology portfolio including Kisqali Phase III NATALEE trial in early breast cancer at ASCO

- Primary analysis of NATALEE, the first and only positive Phase III study of a CDK4/6 inhibitor in a broad population of patients with stage II and III HR+/HER2early breast cancer at risk of recurrence, including those with no nodal involvement, to be presented
- New analyses from the Pluvicto VISION trial in prostate cancer and the JDQ443
  KontRASt-01 trial in KRAS G12C-mutated lung cancer among 40+ Novartis
  abstracts accepted at ASCO, underscoring strength of Novartis oncology portfolio
  and therapeutic platforms

**Basel, April 26, 2023** — Novartis will present new data from its oncology portfolio at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, including advancements in breast cancer, prostate cancer and lung cancer from more than 40 Novartis-sponsored and investigator-led trials. Primary results from the NATALEE trial evaluating Kisqali® (ribociclib) plus endocrine therapy in patients with stage II and stage III hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) early breast cancer at risk of cancer recurrence, regardless of nodal involvement, will be presented.

"We look forward to sharing the primary analysis from the Phase III NATALEE trial of Kisqali in the investigational setting in a broad population of patients with early-stage breast cancer at ASCO," said Shreeram Aradhye, M.D., President, Global Drug Development and Chief Medical Officer, Novartis. "These promising data, together with other key updates, illustrate how we continue to advance our pipeline in oncology, with the potential to help address the significant unmet needs of patients living with cancer."

# Key highlights of data accepted by ASCO include:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Kisqali <sup>®</sup> (ribociclib)*	Phase III NATALEE trial of ribociclib + endocrine therapy as adjuvant treatment in patients with HR+/HER2- early breast cancer	Abstract #LBA500 Oral presentation: Friday, June 2, 2:45 – 5:45pm CDT
Kisqali <sup>®</sup> (ribociclib)*	Outcomes with first-line (1L) ribociclib (RIB) + endocrine therapy (ET) vs physician's choice combination	Abstract #1063 Poster available:

	chemotherapy (combo CT) by age in pre/perimenopausal patients (pts) with aggressive HR+/HER2- advanced breast cancer (ABC): A subgroup analysis of the RIGHT Choice trial	Sunday, June 4, 8:00 – 11:00am CDT
Kisqali <sup>®</sup> (ribociclib)*	Ribociclib (RIB) vs. palbociclib (PAL) in patients (pts) with hormone receptor-positive/HER2-negative/HER2-Enriched (HR+/HER2-/HER2-E) advanced breast cancer (ABC): A head-to-head phase III study. HARMONIA SOLTI-2101 / AFT-58	Abstract #TPS1125 Poster available: Sunday, June 4, 8:00 – 11:00am CDT
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Building a predictive model for outcomes with [177Lu]Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer using VISION data: Preliminary results	Abstract #5028 Poster available: Saturday, June 3, 8:00 – 11:00am CDT
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Tumor dosimetry of [177Lu]Lu-PSMA-617 for the treatment of metastatic castration-resistant prostate cancer: results from the VISION trial sub-study	Abstract #5046 Poster available: Saturday, June 3, 8:00 – 11:00am CDT
JDQ443	KontRASt-01 update: Safety and efficacy of JDQ443 in KRAS G12C-mutated solid tumors including non-small cell lung cancer (NSCLC)	Abstract #9007 Oral presentation: Tuesday, June 6, 9:45am – 12:45pm CDT
PHE885	Updated phase I study results of PHE885, a T-Charge manufactured BCMA-directed CAR-T cell therapy, for patients (pts) with r/r multiple myeloma (RRMM)	Abstract #8004 Oral presentation: Saturday, June 3, 1:15 – 4:15pm CDT

## **Product Information**

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

#### **Disclaimer**

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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**

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. About 103,000 people of more than 140 nationalities work together to bring Novartis products to nearly 800 million people around the world. Find out more at https://www.novartis.com.

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