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MEDIA & INVESTOR RELEASE

Novartis to present new oncology data at ESMO 2023 demonstrating practice-changing innovation in advanced prostate and early breast cancer

- *Key data from the Phase III PSMAfore trial has been selected for a Presidential session; PSMAfore is investigating Pluvicto™ (INN: lutetium (177Lu) vipivotide tetraxetan) in the pre-chemotherapy setting for patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC)*

- *New analysis of key subgroups of clinical interest from NATALEE reinforces the potential of Kisqali® (ribociclib) plus endocrine therapy (ET) to consistently reduce the risk of cancer recurrence across a broad population of patients with stage II and stage III HR+/HER2- early breast cancer, including those with no nodal involvement*

Basel, October 5, 2023 — Novartis will present new data from 29 Novartis and investigator-led abstracts at the European Society for Medical Oncology (ESMO) Congress 2023, highlighting latest developments from across its oncology portfolio and addressing unmet needs of patients diagnosed with some of the most prevalent cancers, including prostate and breast.

Key data from the Phase III PSMAfore trial investigating Pluvicto™ (INN: lutetium (177Lu) vipivotide tetraxetan) as an earlier line of treatment for patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have not been exposed to a taxane-containing regimen will be presented. PSMAfore met its primary endpoint of radiographic progression-free survival (rPFS) in December 2022, and data collection for the key secondary endpoint of overall survival (OS) is ongoing. Data from the primary rPFS analysis and the second interim OS analysis will be presented at ESMO.

“Metastatic prostate cancer has a five-year survival rate of about 30 percent, and patients who progress despite taking androgen-receptor pathway inhibitor therapy need additional treatment options with reduced toxicity,” said Jeff Legos, Executive Vice President, Global Head of Oncology and Hematology Development at Novartis. “Pluvicto is the first and only approved, targeted radioligand therapy to significantly extend life in patients with mCRPC who have been treated with ARPI therapy and taxane-based chemotherapy. We look forward to sharing new data from the Phase III PSMAfore trial, which adds to the growing body of evidence demonstrating the potential of our radioligand therapy platform in earlier lines of therapy.”

Key highlights of data accepted by ESMO include:

Medicine	**Abstract title**	**Presentation Number/ Presentation Details**
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Phase 3 trial of [177Lu]Lu-PSMA-617 in taxane-naïve patients with metastatic castration-resistant prostate cancer (PSMAfore)	Presentation Number #LBA13 Presidential 3 (Proffered Paper session): Monday, October 23, 17:10 – 17:22 CEST
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	First real life data on [177Lu]Lu-PSMA-617: Descriptive analysis on the largest metastatic castration-resistant prostate cancer (mCRPC) cohort treated in early access in France	Presentation Number #1814P Poster available: Sunday, October 22, 9:00 – 17:00 CEST
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Enzalutamide and 177Lu-PSMA-617 in poor-risk metastatic, castration-resistant prostate cancer (mCRPC): a randomized phase 2 trial: ENZA-p (ANZUP 1901)	Presentation Number #LBA84 Proffered Paper session: Friday, October 20, 16:40 – 16:50 CEST
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Prognostic value of neutrophil-to-lymphocyte ratio and lymphopenia in patients with metastatic castration-resistant prostate cancer (mCRPC) treated with [177Lu]Lu-PSMA-617: VISION post-hoc analysis	Presentation Number #1838P Poster available: Sunday, October 22, 9:00 – 17:00 CEST
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Association of health-related quality of life with efficacy outcomes in the VISION study of patients with metastatic castration-resistant prostate cancer	Presentation Number #1810P Poster available: Sunday, October 22, 9:00 – 17:00 CEST
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Molecular features of circulating tumour cells (CTCs) associate with response to 177Lu PSMA 617 plus pembrolizumab for metastatic castration resistant prostate cancer (mCRPC).	Presentation Number #1825P Poster available: Sunday, October 22, 9:00 – 17:00 CEST
Kisqali® (ribociclib)*	Invasive disease-free survival (iDFS) across key subgroups from the Phase III NATALEE study of ribociclib (RIB) + a nonsteroidal aromatase inhibitor (NSAI) in patients (pts) with HR+/HER2- early breast cancer (EBC)	Presentation Number #LBA23 Mini oral session: Monday, October 23, 17:05 – 17:10 CEST
Kisqali® (ribociclib)*	First-line ribociclib (RIB) + endocrine therapy (ET) vs	Presentation Number #402P Poster available:

	combination chemotherapy (combo CT) in aggressive HR+/HER2- advanced breast cancer (ABC): a subgroup analysis of patients (pts) with or without visceral crisis from the Phase II RIGHT Choice study	Saturday, October 21, 9:00 – 17:00 CEST
Kisqali® (ribociclib)*	Quality of life (QOL) analysis from the Phase II RIGHT Choice study of first-line ribociclib (RIB) + endocrine therapy (ET) vs combination chemotherapy (combo CT) in aggressive HR+/HER2- advanced breast cancer (ABC)	Presentation Number #456P Poster available: Saturday, October 21, 9:00 – 17:00 CEST
Lutathera® (lutetium Lu 177 dotatate)	A Prospective Phase II Single-Arm Trial on Neoadjuvant Peptide Receptor Radionuclide Therapy (PRRT) with 177Lu-DOTATATE Followed by Surgery for Pancreatic Neuroendocrine Tumors (NeoLuPaNET)	Presentation Number #1186MO Mini oral session: Sunday, October 22, 17:25 – 17:30 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.

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Novartis is a focused 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.

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

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