Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
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MEDIA & INVESTOR RELEASE

Novartis presents new data in breast and prostate cancer at ESMO

- *Overall survival results from pooled exploratory analysis of MONALEESA trials in patients with aggressive HR+/HER2- advanced breast cancer treated with Kisqali®*
- *Data from VISION study reporting associations between magnitude of PSA decline from baseline and clinical outcomes with Pluvicto® in patients with mCRPC*
- *Overall survival and safety findings for first-line tislelizumab in unresectable hepatocellular carcinoma from RATIONALE 301, the eighth positive clinical trial readout for tislelizumab*

Basel, August 30, 2022 — Novartis will showcase new data from across its oncology portfolio at the European Society for Medical Oncology (ESMO) Congress 2022 with over 35 accepted abstracts from Novartis-sponsored and investigator-initiated trials including new data in advanced breast cancer and metastatic castration-resistant prostate cancer.

“We are excited to share the data being presented across our portfolio of cancer therapies, which reinforce our commitment to pursuing every possible approach to address the urgent and significant unmet medical needs of people living with cancer,” said Jeff Legos, Executive Vice President, Global Head of Oncology & Hematology Development, Novartis. “Our presentations at ESMO will highlight our continued dedication to advancing innovative treatment options for these critical diseases.”

Key highlights of data accepted by ESMO:

Medicine	**Abstract Title**	**Abstract Number/ Presentation Details**
Kisqali® (ribociclib)*	Pooled exploratory analysis of survival in patients (pts) with HR+/HER2− advanced breast cancer (ABC) and visceral metastases (mets) treated with ribociclib (RIB) + endocrine therapy (ET) in the MONALEESA (ML) trials	Abstract #205P Poster Session Saturday, September 10
Kisqali® (ribociclib)*	HARMONIA SOLTI-2101 / AFT-58: A head-to-head phase III study comparing ribociclib (RIB) and palbociclib (PAL) in patients with hormone receptor-positive/HER2-negative/HER2-Enriched (HR+/HER2-/HER2-E) advanced breast cancer (ABC)†	Abstract # 272TiP Poster Session Saturday, September 10

Piqray® (alpelisib)	BYLieve trial (alpelisib [ALP] + endocrine therapy [ET]) versus real-world (RW) standard of care (SOC) in patients (pts) with PIK3CA-mutated (mut), hormone receptor-2 positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced 3 breast cancer (ABC) who progressed on cyclin-dependent kinase 4/6 inhibitor (CDKi) 4 therapy (tx)	Abstract #222P Poster Session Saturday, September 10
Tislelizumab	Final Analysis of RATIONALE-301: Randomized, Phase 3 study of tislelizumab versus sorafenib as first-line treatment for unresectable hepatocellular carcinoma	Abstract #LBA36 Proffered Paper Session Saturday, September 10 09:15 – 09:25 AM CEST
Tislelizumab	Tislelizumab (TIS) versus docetaxel (TAX) as second- or third-line therapy in previously treated patients (pts) with locally advanced non-small cell lung cancer (NSCLC): Asian versus non-Asian subgroup analysis of the RATIONALE-303 study	Abstract #1031P Poster Session Monday, September 12
Pluvicto™ (lutetium ^{177}Lu vipivotide tetraxetan) (formerly referred to as ^{177}Lu-PSMA-617)	Association between prostate-specific antigen decline and clinical outcomes in patients with metastatic castration-resistant prostate cancer in the VISION trial	Abstract #1372P Poster Session Sunday, September 11
Pluvicto™ (lutetium ^{177}Lu vipivotide tetraxetan)	Radiographic progression-free survival correlation with patient-relevant outcomes: a post hoc analysis of time-to-event endpoints of the VISION trial	Abstract #1374P Poster Session Sunday, September 11,
Prostate Cancer	Quality of life across three countries using a large-scale, fully digital survey of patients with prostate cancer	Abstract #1401P Poster Session Sunday, September 11
Canakinumab (ACZ885)	CANOPY-A: phase III study of canakinumab (CAN) as adjuvant therapy in patients (pts) with completely resected non-small cell lung cancer (NSCLC)	Abstract #LBA49 Proffered Paper Session Sunday, September 11 09:20 – 09:30 AM CEST
Vijoice® (alpelisib)	Clinical benefit of alpelisib in pediatric patients with PIK3CA-related overgrowth spectrum (PROS): an EPIK-P1 analysis	Abstract #468P Poster Session Monday, September 12

Product Information
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,” “seek,” “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
Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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* 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

Anja von Treskow
Novartis External Communications
+41 79 392 8697 (mobile)
anja.von_treskow@novartis.com

Michael Billings
Novartis Oncology Communications
+1 862 778 8656 (direct)
+1 201 400 1854 (mobile)
michael.billings@novartis.com

Julie Masow
Novartis US External Communications
+1 862 579 8456
Julie.masow@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Nicole Zinsli-Somm	+41 61 324 3809	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973-876-4912