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MEDIA & INVESTOR RELEASE

Novartis data at ASCO and EHA showcase latest oncology research and innovation, including in breast and prostate cancer

- *Latest in HR+/HER2- metastatic breast cancer, including data on CDK recycling with Kisqali® plus endocrine therapy, further MONALEESA-2 quality of life and overall survival analyses, and a new biomarker analysis of Piqray® plus fulvestrant*
- *Data for Tafinlar® + Mekinist® in pediatric patients with BRAF V600 low-grade glioma to be featured in ASCO official press briefing*
- *First release of 96-week data on Scemblix® in Ph+ CML in chronic phase patients previously treated with ≥2 prior tyrosine kinase inhibitors*
- *Updated next-generation CAR-T T-Charge™ data, and five-year results from ELIANA trial in pediatric and young adult ALL treated with Kymriah®, the first ever CAR-T cell therapy approved*
- *Data from nearly 130 abstracts from Novartis-sponsored and investigator-initiated trials demonstrates Novartis commitment to push the boundaries of science and harness the power of innovation in established and investigational therapies and novel combinations*

Basel, May 12, 2022 — Novartis highlights data from across its oncology portfolio at the upcoming 2022 American Society of Clinical Oncology (ASCO) Annual Meeting and the European Hematology Association (EHA) 2022 Hybrid Congress. With nearly 130 abstracts from Novartis-sponsored and investigator-initiated trials accepted, the data showcase research across over 20 compounds in key disease areas, including breast, lung and prostate cancers, leukemia, lymphoma, multiple myeloma and other blood disorders.

“We continue to push the boundaries of science with advanced therapies and novel combinations to help address the individual needs of patients,” said Marie-France Tschudin, President, Innovative Medicines International and Chief Commercial Officer, Novartis. “We are particularly excited about the latest data on CDK recycling with Kisqali, and first results for Tafinlar + Mekinist in a rare pediatric brain cancer.”

Key highlights of data accepted by ASCO:

Medicine	Abstract Title	Abstract Number/ Presentation Details
Kisqali® (ribociclib)*	A randomized phase II trial of fulvestrant or exemestane with or without ribociclib after progression on	Abstract # LBA1004 Oral Presentation:

	anti-estrogen therapy plus cyclin-dependent kinase 4/6 inhibition (CDK 4/6i) in patients (pts) with unresectable or hormone receptor positive (HR+), HER2 negative metastatic breast cancer (MBC): MAINTAIN trial†	Saturday, June 4, 1:15 PM – 4:15 PM CDT
Kisqali® (ribociclib)*	Impact of ribociclib (RIB) dose modifications (mod) on overall survival (OS) in patients (pts) with HR+/HER2− advanced breast cancer (ABC) in MONALEESA (ML)-2	Abstract #1017 Poster Discussion: Monday, June 6, 8:00 AM – 11:00 AM CDT
Kisqali® (ribociclib)*	Quality of life (QOL) with ribociclib (RIB) plus aromatase inhibitor (AI) vs abemaciclib (ABE) plus AI as first-line (1L) treatment (tx) of hormone receptor–positive/human epidermal growth factor receptor–negative (HR+/HER2−) advanced breast cancer (ABC), assessed via matching-adjusted indirect comparison (MAIC)	Abstract #1015 Poster Discussion: Monday, June 6, 8:00 AM – 11:00 AM CDT
Piqray® (alpelisib)	Alpelisib (ALP) + Fulvestrant (FUL) in Patients (pts) With Hormone Receptor-Positive (HR+), Human Epidermal Growth Factor Receptor 2-Negative (HER2−), Advanced Breast Cancer (ABC): Biomarker (BM) Analyses by Next-Generation Sequencing (NGS) From the SOLAR-1 Study	Abstract #1006 Oral Presentation: Saturday, June 4, 1:15 PM – 4:15 PM CDT
Piqray® (alpelisib)	Alpelisib (ALP) + endocrine therapy (ET) in patients (pts) with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–), PIK3CA-mutated (mut) advanced breast cancer (ABC): Baseline biomarker analysis and progression-free survival (PFS) by duration of prior cyclin-dependent kinase 4/6 inhibitor (CDK4/6i) therapy in the BYLieve study	Abstract #1018 Poster Discussion: Monday, June 6, 8:00 AM – 11:00 AM CDT
Scemblix® (asciminib)	Efficacy and safety results from ASCEMBL, a phase 3 study of asciminib vs bosutinib (BOS) in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) after ≥2 prior tyrosine kinase inhibitors (TKIs): wk 96 update	Abstract #7004 Oral Presentation: Tuesday, June 7, 9:45 AM – 12:45 PM CDT
Tafinlar® (dabrafenib) / Mekinist® (trametinib)	Primary analysis of a phase II trial of dabrafenib + trametinib (dab + tram) in BRAF V600–mutant pediatric low-grade glioma (pLGG)	Abstract #2002 Oral Presentation: Monday, June 6, 11:30 AM – 2:30 PM CDT
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	^{177}Lu-PSMA-617 in PSMA-positive metastatic castration-resistant prostate cancer: prior and concomitant	Abstract #5001 Oral Presentation: Sunday, June 5, 8:00 AM – 11:00 AM CDT

(formerly referred to as ^{177}Lu-PSMA-617)	treatment subgroup analyses of the VISION trial	
Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan)	Tolerability of ^{177}Lu-PSMA-617 by treatment exposure in patients with metastatic castration-resistant prostate cancer (mCRPC): a VISION study subgroup analysis	Abstract #5047 Poster available: Monday, June 6, 1:15 PM – 4:15 PM CDT
Locametz® (kit for the preparation of gallium Ga 68 gozetotide injection)**	^{68}Ga-PSMA-11 PET baseline imaging as a prognostic tool for clinical outcomes to ^{177}Lu-PSMA-617 in patients with mCRPC: a VISION sub-study	Abstract #5002 Oral Presentation: Sunday, June 5, 8:00 AM – 11:00 AM CDT
Lutathera® (lutetium Lu 177 dotatate)***	Effectiveness and safety of re-treatment with lutetium Lu 177 dotatate in patients with progressive neuroendocrine tumors in the United States: a retrospective real-world study	Abstract #e16215

Key highlights of data accepted by EHA:

Medicine	**Abstract Title**	**Abstract Number/ Presentation Details**
Scemblix® (asciminib)	Efficacy and safety results from ASCEMBL, a phase 3 study of asciminib vs bosutinib in patients with chronic myeloid leukemia in chronic phase after ≥2 prior tyrosine kinase inhibitors: week 96 update	Abstract #S155 Oral Presentation: Sunday, June 12, 11:30 AM – 12:45 PM CEST
Scemblix® (asciminib)	Asciminib provides durable molecular responses in patients (Pts) with chronic myeloid leukemia in chronic phase (CML-CP) with the T315I mutation: Updated efficacy and safety data from a Phase 1 trial	Abstract #P704 Poster Available: Friday, June 10, 4:30 PM – 5:45 PM CEST
Kymriah® (tisagenlecleucel)	Tisagenlecleucel in pediatric and young adult patients (Pts) with relapsed/refractory (R/R) B-cell acute lymphoblastic leukemia (B-ALL): Final analyses from the ELIANA study	Abstract #S112 Oral Presentation: Sunday, June 12, 11:30 AM – 12:45 PM CEST
YTB323	Phase I study of YTB323, a chimeric antigen receptor (CAR)-T cell therapy manufactured using T-Charge™, in patients with relapsed/refractory diffuse large B-cell lymphoma	Abstract #S212 Oral Presentation: Saturday, June 11, 11:30 AM – 12:45 PM CEST
PHE885	Phase I study data update of PHE885, a fully human BCMA-directed CAR-T cell therapy manufactured using the T-Charge™ platform for patients with relapsed/refractory (R/R) multiple myeloma (MM)	Abstract #P1446 Poster Available: Friday, June 10, 4:30 PM – 5:45 PM CEST

Sabatolimab	First results of a Phase II study (STIMULUS-AML1) investigating sabatolimab + azacitidine + venetoclax in patients with newly diagnosed acute myeloid leukemia	Abstract #P582 Poster available: Friday, June 10, 4:30 PM – 5:45 PM CEST
Promacta/Revolade® (eltrombopag)	Sustained response off treatment in eltrombopag-treated patients with ITP who are refractory or relapsed after first-line steroids: primary analysis of the phase II TAPER trial	Abstract #S292 Oral Presentation Saturday, June 11, 11:30 AM – 12:45 PM CEST

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.

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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.

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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

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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
** Locametz is a registered trademark of Advanced Accelerator Applications, a Novartis company.
*** Lutathera is a registered trademark of Advanced Accelerator Applications, a Novartis company.

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