

## **MEDIA & INVESTOR RELEASE**

### **Novartis to unveil new data at ASCO and EHA from its robust portfolio, including overall survival in prostate and breast cancer**

- *Overall survival and radiographic PFS from phase III study of investigational radioligand therapy <sup>177</sup>Lu-PSMA-617 VISION trial of patients with metastatic castration-resistant prostate cancer to be presented at ASCO plenary*
- *New Kisqali (ribociclib)\* overall survival data from extended follow-up of MONALEESA-3 trial in patients with postmenopausal HR+/HER2- advanced or metastatic breast cancer*
- *Phase II results for oral, targeted factor B inhibitor iptacopan (LNP023) as first line monotherapy in anti-C5 treatment-naïve patients with paroxysmal nocturnal hemoglobinuria*
- *Updated efficacy and safety results from pivotal ELARA trial of Kymriah® (tisagenlecleucel) in relapsed or refractory follicular lymphoma*
- *Data demonstrate Novartis innovation for patients and strength of its four therapeutic platforms: targeted therapies, radioligand therapy, cell and gene therapy and immunotherapy*

**Basel, May 19, 2021** — Novartis will present new data from its portfolio of approved and investigational targeted, radioligand, cell and gene and immunotherapies at the upcoming 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and the 2021 European Hematology Association (EHA) Virtual Congress. More than 110 abstracts, including Novartis-sponsored and investigator-initiated trials, will be presented at the meetings.

“Our bold ambition is to extend and improve the lives of those living with cancer and serious blood disorders, and ultimately find cures,” said Susanne Schaffert, PhD, President, Novartis Oncology. “These exciting data from across our four therapeutic platforms illustrate how we are uniquely positioned to deliver transformative innovations that may bring renewed hope for patients.”

## Key highlights of data accepted by ASCO:

- Efficacy and safety results from Phase III VISION study of investigational targeted radioligand therapy <sup>177</sup>Lu-PSMA-617
  - Phase 3 study of <sup>177</sup>Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer (VISION) [Abstract #LBA4; oral presentation (plenary): Sunday, June 6, 1:00 PM EDT]
- Kisqali® (ribociclib)\* overall survival analysis from MONALEESA-3
  - Updated overall survival (OS) results from the Phase III MONALEESA-3 trial of postmenopausal patients (pts) with HR+/HER2- advanced breast cancer (ABC) treated with fulvestrant (FUL) ± ribociclib (RIB) [Abstract #1001; oral presentation: Saturday, June 5, 1:30 PM EDT]
- Piqray® (alpelisib) long-term disease control data from SOLAR-1
  - Long-term (LT) Disease Control in Patients (pts) With Hormone Receptor-Positive (HR+), PIK3CA-Altered Advanced Breast Cancer (ABC) Treated With Alpelisib (ALP) + Fulvestrant (FUL) [Abstract #1054; poster session: Friday, June 4, 9:00 AM EDT]
- Kymriah® (tisagenlecleucel) updated efficacy and safety results from Phase II ELARA trial in patients with relapsed or refractory follicular lymphoma
  - Efficacy and Safety of Tisagenlecleucel (Tisa-cel) in Adult Patients (Pts) With Relapsed/Refractory Follicular Lymphoma (r/r FL): Primary Analysis of the Phase 2 ELARA Trial [ASCO: Abstract #7508; oral presentation: Monday, June 7, 11:30 AM EDT] / [EHA encore: Abstract #S210; oral presentation: Friday, June 11, 9:00 AM CEST]
- Investigational agent tislelizumab\*\* RATIONALE 302 pivotal data in advanced/unresectable metastatic esophageal squamous cell carcinoma and Phase II data in patients with MSI-H or dMMR solid tumors
  - RATIONALE 302: Randomized, phase 3 study of tislelizumab versus chemotherapy as second-line treatment for advanced unresectable/metastatic esophageal squamous cell carcinoma [Abstract #4012; poster discussion: Friday, June 4, 9:00 AM EDT]
  - A phase 2 study of tislelizumab monotherapy in patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high/mismatch repair deficient solid tumors [Abstract #2569; poster discussion: Friday, June 4, 9:00 AM EDT]
- Early data demonstrating innovation in solid tumors with novel assets TNO155 and NIS793; further combination studies and NIS793 Phase III planned to start later this year
  - Initial results from a dose finding study of TNO155, a SHP2 inhibitor, in adults with advanced solid tumors [Abstract #3005; oral abstract: Friday, June 4, 11:00 AM EDT]
  - Phase Ib study of the anti-TGF-β monoclonal antibody (mAb) NIS793 combined with spartalizumab (PDR001), a PD-1 inhibitor, in patients (pts) with advanced solid tumors [Abstract #2509; poster session: Friday, June 4, 9:00 AM EDT]
- Analysis of pyrexia-related and efficacy outcomes with new pyrexia management algorithm in patients with stage III BRAF-mutation positive melanoma treated with adjuvant Tafinlar® (dabrafenib) and Mekinist® (trametinib)
  - Improved pyrexia-related outcomes associated with an adapted pyrexia adverse event (AE) management algorithm in patients (pts) treated with adjuvant dabrafenib + trametinib (dab + tram): Primary results of COMBI-APlus [Abstract #9525; poster session: Friday, June 4, 9:00 AM EDT]

- Tabrecta® (capmatinib)\*\*\* updated analysis from Phase II GEOMETRY mono-1 trial
  - Capmatinib in MET exon 14-mutated, advanced NSCLC: Updated results from the GEOMETRY mono-1 study [Abstract #9020; poster session: Friday, June 4, 9:00 AM EDT]
- Lutathera® (lutetium Lu 177 dotatate)\*\*\*\* final overall survival data from Phase III NETTER-1 study in adults with somatostatin receptor-positive midgut neuroendocrine tumors
  - Final overall survival in the phase 3 NETTER-1 study of <sup>177</sup>Lu-DOTATATE in patients with midgut neuroendocrine tumors [Abstract #4112; poster session: Friday, June 4, 9:00 AM EDT]

#### **Key highlights of data accepted by EHA:**

- Iptacopan (LNP023) efficacy and safety results from Phase II oral monotherapy trial as first-line treatment in patients with paroxysmal nocturnal hemoglobinuria
  - First-Line Treatment of PNH Patients With Iptacopan Leads to Rapid and Durable Hemoglobin Increase by Controlling Both Intra- and Extra-Vascular Hemolysis [Abstract #S173; oral presentation: Friday, June 11, 9:00 AM CEST]
- Subgroup analyses of REACH2 trial evaluating Jakavi® (ruxolitinib)\*\*\*\*\* in acute graft-versus-host disease
  - Efficacy and Safety of Ruxolitinib in Patients With Steroid-Refractory Acute Graft-Vs-Host Disease After Crossover in the Phase 3 REACH2 Study [Abstract #S236; oral presentation: Friday, June 11, 9:00 AM CEST]
- Results from X2105 study of sabatolimab (MBG453), a novel immuno-myeloid therapy targeting TIM-3, in patients with a myelodysplastic syndromes and acute myeloid leukemia
  - Sabatolimab Plus Hypomethylating Agents (HMAs) in Patients (Pts) With High-/Very High-risk Myelodysplastic Syndrome (HR/vHR-MDS) and Acute Myeloid Leukemia (AML): Subgroup Analysis of a Phase 1 Study [Abstract #S168; oral presentation: Friday, June 11, 9:00 AM CEST]
- Safety and efficacy results from the Phase II SOAR trial evaluating Promacta®/Revolade® (eltrombopag) in patients with severe acquired aplastic anemia who cannot use ATG
  - An Interventional, Phase 2, Single-Arm Study to Assess the Efficacy and Safety of Eltrombopag Combined with Cyclosporine as First-Line Therapy in Adults with Severe Acquired Aplastic Anemia (SOAR) [Abstract #S172; oral presentation: Friday, June 11, 9:00 AM CEST]

#### **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.novartis oncology.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 110,000 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.

\*\* In January 2021 BeiGene granted Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan through a collaboration and license agreement.

\*\*\* Tabrecta is an oral and selective MET inhibitor licensed to Novartis by Incyte Corporation in 2009. Under the Agreement, Incyte granted Novartis worldwide exclusive development and commercialization rights to capmatinib and certain back-up compounds in all indications.

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

\*\*\*\*\* Jakavi is a registered trademark of Novartis AG in countries outside the United States. Jakafi is a registered trademark of Incyte Corporation. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the United States.

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