

MEDIA & INVESTOR RELEASE

Novartis data at ASCO and EHA showcase bold approaches to reimagine cancer and blood disorders through multiple therapeutic platforms

- *New Kisqali[®] (ribociclib)* overall survival subgroup analysis in HR+/HER2- advanced breast cancer (ABC) and additional Piqray[®] (alpelisib) data in patients in HR+/HER2- ABC patients with a PIK3CA mutation*
- *Results from five-year adjuvant treatment study among BRAF+ melanoma patients taking Tafinlar[®]+Mekinist[®] (dabrafenib+trametinib) after surgical removal of their cancer*
- *New data in non-small cell lung cancer, including efficacy and safety data for recently FDA-approved, targeted therapy Tabrecta[™] (capmatinib)** and Phase III trial updates for the investigational immunotherapy canakinumab*
- *Data updates on the dual targeting, anti-TIM-3 monoclonal antibody MBG453 in high-risk myelodysplastic syndrome and acute myeloid leukemia, and the STAMP-inhibitor asciminib (ABL001) in chronic myeloid leukemia*

Basel, May 14, 2020 — Data from more than 110 abstracts, including Novartis-sponsored and investigator-initiated trials, will be presented during the upcoming American Society of Clinical Oncology ASCO20 Virtual Scientific Program and the European Hematology Association EHA25 Virtual Congress. The ASCO and EHA meetings will be held May 29-31, and June 11-14, respectively.

“We are living in a world of uncertainty, but cancer won’t wait. Now, more than ever, we need to continue to be bold together. Our data at ASCO and EHA highlight our unique approach to harnessing the power of multiple treatment platforms to deliver transformative medicines to people living with cancer and blood disorders,” said Susanne Schaffert, PhD, President, Novartis Oncology. “We look forward to ‘seeing’ everyone virtually at the congresses and helping participants access key data and information through our dedicated congress portals.”

Key highlights of data accepted by ASCO:

- Kisqali overall survival subgroup analysis from MONALEESA-3 and -7 trials, and results on Piqray plus fulvestrant in ABC patients with a PIK3CA mutation from the BYLieve study:
 - Overall survival in patients with ABC with visceral metastases (mets), including those with liver mets, treated with ribociclib plus endocrine therapy in the MONALEESA-3 and -7 trials [Abstract # 1054; poster 139]

- Alpelisib + fulvestrant in patients with PIK3CA-mutated HR+/HER2- ABC previously treated with cyclin-dependent kinase 4/6 inhibitor + aromatase inhibitor: BYLieve Study Results [Abstract #1006; oral presentation]
- Five-year Tafinlar+Mekinist data in the adjuvant treatment of BRAFV600-mutated melanoma, and updated data in combination with immune checkpoint inhibitor spartalizumab (PDR001):
 - Long-term benefit of adjuvant dabrafenib+trametinib in patients with resected stage III BRAF V600-mutant melanoma: 5-year analysis of COMBI-AD [Abstract #10001; oral presentation]
 - The anti-PD-1 antibody spartalizumab in combination with dabrafenib and trametinib in advanced BRAF V600-mutant melanoma: efficacy and safety findings from Parts 1 and 2 of the Phase III COMBI-i trial [Abstract #10028; poster 377]
- Tavegyl data updates from multiple analyses from the GEOMETRY study among patients with METex14-mutated and MET-amplified advanced non-small cell lung cancer (NSCLC):
 - Capmatinib in patients with METex14-mutated advanced NSCLC who received prior immunotherapy: results from the Phase 2 GEOMETRY Mono-1 study [Abstract #9509; oral presentation]
 - Capmatinib in patients with METex14-mutated or high MET-amplified advanced NSCLC: results from Cohort 6 of the phase 2 GEOMETRY mono-1 study [Abstract #9520; poster 286]
- Safety data from a US expanded access program with radioligand therapy Lutathera® (lutetium Lu 177 dotatate)*** in patients with advanced neuroendocrine tumors (NETs):
 - Safety of ¹⁷⁷Lu-DOTATATE in patients with advanced NETs: data from a US expanded access program [Abstract #4604; poster 212]
- Learnings from the inclusion of patient insights in the research and development process, through the Novartis Global Oncology Patient Insight Panels (GOPIPs):
 - Patient engagement in clinical trial design and implementation: A pragmatic approach to valued insights [Abstract #e14084; online publication]

In addition, TheraP, sponsored by the Australian & New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group, comparing investigational radioligand therapy ¹⁷⁷Lu-PSMA-617 to cabazitaxel in patients with metastatic castration resistant prostate cancer (mCRPC) progressing after docetaxel, will be presented:

- TheraP: A randomised phase II trial of LuPSMA theranostic versus cabazitaxel in mCRPC progressing after docetaxel: Initial results (ANZUP protocol 1603) [Abstract #5500; oral presentation]

Key highlights of data accepted by EHA:

- Efficacy and safety data on the investigational anti-TIM-3 monoclonal antibody MBG453, which targets both immune and myeloid cells in patients with high-risk myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML):
 - Anti-TIM-3 antibody MBG453 in combination with hypomethylating agents in patients with high-risk MDS and AML: a Phase 1 study [Abstract #S185; oral presentation; Sunday, June 14, 8:00 AM CEST]
- A longer term Phase I safety and efficacy analysis of asciminib, an investigational treatment specifically targeting the BCR-ABL myristoyl pocket (STAMP), in heavily pre-treated patients with chronic myeloid leukemia (CML):

- Asciminib in heavily pretreated patients with Philadelphia chromosome-positive (Ph+) CML in chronic phase sensitive to TKI therapy [Abstract #S170; oral presentation; Friday, June 12, 08:30 AM CEST]
- Efficacy results in patients with acute graft-versus-host disease (GvHD) treated with Jakavi® (ruxolitinib)****:
 - Ruxolitinib versus best available therapy in patients with steroid-refractory acute GvHD: overall response rate by baseline characteristics in the randomized Phase 3 REACH2 trial [Abstract #S255; oral presentation; Friday, June 12, 8:00 AM CEST]

More information, including the list of Novartis-sponsored abstracts, and access to the presentations for registered participants will be available on <https://www.virtualcongress.novartis.com/ASCO20>, starting on May 28, and on <https://www.virtualcongress.novartis.com/EHA25>, by June 11.

Disclaimer

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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 109,000 people of more than 145 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.

** 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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