Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
https://twitter.com/novartisnews

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]

- Tabrecta 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 ^{177}Lu-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 ^{177}Lu-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, 8:30 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
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 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at **https://twitter.com/novartisnews**
For Novartis multimedia content, please visit **https://www.novartis.com/news/media-library**
For questions about the site or required registration, please contact media.relations@novartis.com

# # #

* 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.

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

Julie Masow
Novartis Oncology Media Relations
+1 862 778 7220 (direct)
+1 862 579 8456 (mobile)
julie.masow@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@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	+1 862 778 5052
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 862 778 3258
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		