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Novartis data at ASCO and EHA demonstrate novel approaches to reimagining medicine in cancer and serious blood disorders

- *Overall survival results from MONALEESA-7 with Kisqali® (ribociclib)* plus endocrine therapy in premenopausal women with HR+/HER2- advanced breast cancer, to be presented at ASCO*
- *Primary results of GEOMETRY study for capmatinib (INC280)** in METΔex14-mutated advanced non-small cell lung cancer (NSCLC) at ASCO*
- *Five-year efficacy and safety updates for Tafinlar+Mekinist® (dabrafenib + trametinib) in patients with BRAF V600-mutant unresectable or metastatic melanoma, featured at ASCO*
- *Both Congresses to highlight Tasigna® (nilotinib) treatment-free remission trial updates after more than 3.7 years of follow-up and the investigational compound asciminib (ABL001) combination data in chronic myeloid leukemia (CML)*

Basel, May 16, 2019 – Novartis will present data from across its oncology portfolio at the upcoming 55th Annual Meeting of the American Society of Clinical Oncology (ASCO), taking place May 31-June 4 in Chicago; and the 24th Annual Congress of the European Hematology Association (EHA), scheduled for June 13-16 in Amsterdam. The more than 100 abstracts to be presented underscore Novartis' relentless commitment to addressing unmet needs in cancer and hematology through innovation and research. Data will focus on a range of disease areas, including breast cancer, lung cancer, melanoma and sickle cell disease, as well as leukemias, other hematologic disorders and solid tumors.

"We are excited to share the latest information about our transformative therapies in cancer and serious blood disorders at ASCO and EHA this year," said Susanne Schaffert, CEO, Novartis Oncology. "New data will showcase our scientific and patient-focused prowess across a range of the most difficult-to-treat diseases in the world."

Novartis data at the 2019 ASCO Annual Congress will highlight the following:

Kisqali overall survival results, and additional data on treatment sequencing and patient reported outcomes in HR+/HER2- advanced breast cancer:

- Phase III MONALEESA-7 trial of premenopausal patients with HR+/HER2- advanced breast cancer (ABC) treated with endocrine therapy ± ribociclib: Overall survival (OS) results [Abstract # LBA1008; Oral presentation: Tuesday, June 4, 11:57 AM CDT]
- Interim results in the full population from CompLEEment-1, a phase 3b study of ribociclib and letrozole as first-line therapy for advanced breast cancer in an expanded population [Abstract #1041; Sunday, June 2, 8:00 AM CDT]
- Alpelisib (ALP) + endocrine therapy (ET) in patients with PIK3CA-mutated hormone-receptor positive (HR+), human epidermal growth factor-2-negative (HER2-) advanced breast cancer (ABC): First interim BYLieve results [Abstract #1040; Sunday, June 2, 8:00 AM CDT]

- Patient-reported outcomes (PROs) in patients with PIK3CA-mutated hormone receptor-positive (HR+), human epidermal growth factor receptor-2-negative (HER2-) advanced breast cancer (ABC) from SOLAR-1 [Abstract #1039; Sunday, June 2, 8:00 AM CDT]
- Alpelisib (ALP) + fulvestrant (FUL) in patients with PIK3CA-mutated hormone receptor-positive (HR+), human epidermal growth factor receptor-2-negative (HER2-) advanced breast cancer (ABC): SOLAR-1 results by therapy line and endocrine therapy resistance (ETR) [Abstract #1038; Sunday, June 2, 8:00 AM CDT]
- NATALEE: Phase 3 study of ribociclib (RIBO) + endocrine therapy (ET) as adjuvant treatment in hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (EBC) [Abstract #TPS597; Sunday, June 2, 8:00 AM CDT]
- First-line ribociclib plus letrozole for postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2-) advanced breast cancer (ABC): MONALEESA-2 long-term safety results [Abstract #1078; Sunday, June 2, 8:00 AM CDT]
- Continuous dosing ribociclib, everolimus, exemestane in HR+ and HER2- advanced breast cancer post-progression on a CDK4/6 inhibitor [Abstract #1016; Sunday, June 2, 8:00 AM CDT, Poster discussion: 11:15 AM CDT]
- In-depth gene expression analysis of premenopausal patients with HR+/HER2- advanced breast cancer (ABC) treated with ribociclib containing therapy in the Phase III MONALEESA-7 trial [Abstract #1018; Sunday, June 2, 11:15 AM CDT, Poster discussion: 11:30 AM CDT]

Long-term and new analyses of the Tafinlar+Mekinist COMBI trials in melanoma:

- Five-year analysis of dabrafenib plus trametinib (D+T) in patients with *BRAF* V600-mutant unresectable or metastatic melanoma confirms long-term benefit [Abstract #9507; Oral presentation: Tuesday, June 4, 11:57 AM CDT]
- The anti–PD-1 antibody spartalizumab (S) in combination with dabrafenib (D) and trametinib (T) in previously untreated patients with advanced *BRAF* V600-mutant melanoma: updated efficacy and safety from parts 1 and 2 of COMBI-i [Abstract #9531; Monday, June 3, 1:15 PM CDT]
- Circulating tumor DNA (ctDNA) kinetics to predict survival in patients with unresectable or metastatic melanoma treated with dabrafenib (D) or D + trametinib (T) [Abstract #9510; Oral presentation: Saturday, June 1, 3:24 PM CDT]
- Tumor microenvironment (TME), longitudinal biomarker changes, and clinical outcome in patients with advanced *BRAF* V600-mutant melanoma treated with 1st-line spartalizumab (S) + dabrafenib (D) + trametinib (T) [Abstract #9515; Monday, June 3, 1:15 PM CDT; Poster discussion: 4:30 PM CDT]
- Association between baseline disease characteristics and relapse-free survival (RFS) in patients with *BRAF* V600-mutant resected stage III melanoma treated with adjuvant dabrafenib (D) + trametinib (T) or placebo (PBO) [Abstract #9582; Monday, June 3, 1:15 PM CDT]

Results from GEOMETRY study investigating capmatinib (INC280) in NSCLC:

- Capmatinib (INC280) in *METΔex14*-mutated advanced non-small cell lung cancer (NSCLC): Efficacy data from the phase II GEOMETRY mono-1 study [Abstract #9004; Oral presentation: Monday, June 3, 9:12 AM CDT]

Analyses on treatment of advanced solid tumors and hematologic malignancies with spartalizumab (PDR001) in combination with other agents:

- Phase Ib study of MIW815 (ADU-S100) in combination with spartalizumab (PDR001) in patients with advanced/metastatic solid tumors or lymphoma [Abstract #2507; Oral presentation: Sunday, June 2, 10:12 AM CDT]
- Phase II, open-label study of spartalizumab (PDR001) and LAG525 for patients with advanced solid tumors and hematologic malignancies [Abstract #2553; Saturday, June 1, 8:00 AM CDT]

A study evaluating Kymriah® (tisagenlecleucel) in follicular lymphoma:***

- ELARA: A Phase 2, single-arm, multicenter, open-label trial investigating the efficacy and safety of tisagenlecleucel in adult patients with refractory/relapsed follicular lymphoma (r/r FL) [Abstract #TPS7573; Monday, June 3, 8:00 AM CDT]

Long-term treatment-free remission (TFR) data, after Tasigna treatment discontinuation, in patients with CML:

- ENESTop 192-week results: treatment-free remission (TFR) in patients with chronic myeloid leukemia in chronic phase (CML-CP) after stopping second-line (2L) nilotinib (NIL) [Abstract #7005; Oral presentation: Saturday, June 1, 4:24 PM CDT]
- Treatment-free remission (TFR) following frontline (1L) nilotinib (NIL) in patients with chronic myeloid leukemia in chronic phase (CML-CP): 192-week data from the ENESTfreedom study [Abstract #7013; Monday, June 3, 1:15 PM CDT, Poster discussion: 4:30 PM CDT]

Additional data presented at ASCO include:

- The CANOPY Program: Canakinumab in patients with non-small cell lung cancer (NSCLC) [Abstract #TPS9124; Sunday, June 2, 8:00 AM CDT]
- CANOPY-A: A Phase 3 study of canakinumab as adjuvant therapy in patients with surgically resected non-small cell lung cancer (NSCLC) [Abstract #7013; Sunday, June 2, 8:00 AM CDT]

Advanced Accelerator Applications, a Novartis company and leader in nuclear medicine theragnostics, will present additional analyses from the NETTER-1 study evaluating Lutathera® (lutetium Lu 177 dotatate)** in patients with progressive midgut neuroendocrine tumors:**

- Analyses of patient diaries in the NETTER-1 study of 177Lu-DOTATATE versus high-dose octreotide in progressive midgut neuroendocrine tumors [Abstract #4111; Monday, June 3, 8:00 AM CDT]

Sandoz, a Novartis division, the pioneer and global leader in biosimilars, will present data for the company's biosimilar pegfilgrastim:

- Cost-minimization analysis for biosimilar pegfilgrastim in the prophylaxis of chemotherapy induced (febrile) neutropenia and expanded access based on budget neutral basis [Abstract #6645; Saturday, June 1, 1:15 PM CDT]

Additional data from Sandoz to be featured online by ASCO include:

- A large multi-center, randomized, double-blind, crossover study in healthy volunteers, comparing pharmacokinetics and pharmacodynamics of Sandoz proposed biosimilar pegfilgrastim with EU and US reference pegfilgrastim [online only]

Novartis data at the 2019 EHA Annual Congress will highlight the following:

Retrospective data for investigational compound crizanlizumab (SEG101):

- SUCCESSOR: A multicenter retrospective non-interventional follow-up study in patients with sickle cell pain crises who previously participated in the SUSTAIN trial in the United States SUCCESSOR study [Abstract #S853; Oral presentation: Saturday, June 15, 11:45 AM CET]

Expert consensus paper on tapering and discontinuation of TPO-RAs and additional results of worldwide ITP impact survey:

- Tapering and discontinuation of thrombopoietin receptor agonists in ITP: Expert consensus opinions [Abstract #PF709; Friday, June 14, 5:30 PM CET]
- Physicians' perceptions on causes of primary and secondary ITP and leading causes of misdiagnosis: Results from the ITP World Impact Survey (I-WISh) [Abstract #PF712; Friday, June 14, 5:30 PM CET]

- Patient perceptions on splenectomy outcomes: Results from the ITP World Impact Survey (I-WISh) [Abstract #PF714; Friday, June 14, 5:30 PM CET]
- Differences on perceptions on treatment approaches between physicians and ITP patients: Results from the ITP World Impact Survey (I-WISh) [Abstract #PF711; Friday, June 14, 5:30 PM CET]

Data on the investigational compound asciminib (ABL001) in combination with other tyrosine kinase inhibitors in previously treated CML patients:

- Combination therapy using asciminib plus imatinib (IMA) in patients with chronic myeloid leukemia (CML): Results from a Phase 1 study [Abstract #S883; Oral presentation: Saturday, June 15, 4:30 PM CET]
- Combination of asciminib plus nilotinib (NIL) or dasatinib (DAS) in patients with chronic myeloid leukemia: Results from a Phase 1 study [Abstract #S884; Oral presentation: June 15, 4:30 PM CET]

Data analyses with a 3.7-year follow-up for Tasigna TFR in CML:

- Durability and impact on quality of life of treatment-free remission (TFR) in patients with chronic myeloid leukemia after stopping frontline (1L) nilotinib: [Abstract #PF409; Friday, June 14, 5:30 PM CET]
- ENESTop 192-week results: Durability and impact on quality of life of TFR second-line (2L) nilotinib [Abstract #PF411; Friday, June 14, 5:30 PM CET]

Abstracts analyzing the safety and efficacy of Kymriah in acute lymphoblastic leukemia, and on regrading of adverse events in diffuse large B-cell lymphoma:

- Tisagenlecleucel appears effective and safe in pediatric and young adult patients with relapsed/refractory acute lymphoblastic leukemia with high-risk cytogenetic abnormalities [Abstract #S1618; Oral presentation: Sunday, June 16, 8:15 AM CET]
- Analyses of cytokine release syndrome and neurotoxicity by age and lymphodepleting chemotherapy use in adults with relapsed or refractory diffuse large B-cell lymphoma treated with tisagenlecleucel [Abstract #PF305; Friday, June 14, 5:30 PM CET]

Safety and efficacy of Jakavi® (ruxolitinib)** in* myelofibrosis (MF) and anemia, and additional results from a large-scale survey on the impact of myeloproliferative neoplasms:**

- Safety and efficacy of ruxolitinib (RUX) in patients with myelofibrosis (MF) and anemia (HB <10 g/dl): Results at week 24 of the REALISE trial [Abstract #PS1465; Saturday, June 15, 5:30 PM CET]
- Impact of myeloproliferative neoplasms (MPNs) and perceptions of treatment goals amongst physicians and patients in 6 countries: An expansion of the MPN Landmark Survey [Abstract #PF681; Friday, June 14, 5:30 PM CET]

New and updated data evaluating the efficacy and safety of Rydapt® (midostaurin) in patients with acute myeloid leukemia (AML) and different genetic mutational status:

- RATIFY post-hoc analyses:
  - Prognostic and predictive impact of *NPM1*/*FLT3*-ITD genotypes as defined by 2017 European LeukemiaNet (ELN) risk categorization from randomized patients with acute myeloid leukemia (AML) treated within the international RATIFY Study (ALLIANCE 10603) [Abstract #PF260; Friday, June 14, 5:30 PM CET]
  - Genetic landscape of *FLT3*-mutated acute myeloid leukemia (AML) patients treated within the RATIFY Trial: CALGB 10603 (ALLIANCE) [Abstract #PS968; Saturday, June 15, 5:30 PM CET]
  - RATIFY: Prognostic impact of *FLT3* tyrosine kinase domain (TKD) and *NPM1* mutation status in patients with newly diagnosed acute myeloid leukemia (AML) treated with midostaurin + standard chemotherapy [Abstract #PF256; Friday, June 14, 5:30 PM CET]

Throughout the 2019 ASCO Annual Meeting and EHA Annual Meeting, Novartis will host dedicated content on Twitter, Facebook, and LinkedIn, featuring leader and patient insights and perspectives on the emerging trends in cancer care and research.

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.novartisoncology.com/news/product-portfolio.

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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 105 000 people of more than 140 nationalities work at Novartis around the world. Find out more at 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.
** Capmatinib (INC280) is an investigational, 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.
*** Novartis and the University of Pennsylvania's Perelman School of Medicine (Penn) have a global collaboration to research, develop and commercialize chimeric antigen receptor T cell (CAR-T) therapies, including Kymriah, for the investigational treatment of cancers.
**** 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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