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Novartis data at ASCO and EHA reinforce company's commitment to reimagining cancer

May 17, 2018

- - Results from the Kisqali® MONALEESA clinical trial program, the largest industry-sponsored Phase III registration program researching a CDK4/6 inhibitor in HR+/HER2- advanced breast cancer, will be presented at ASCO
- - Long-term analyses of Tasigna® Treatment-free Remission (TFR) studies in Ph+ CML-CP to be featured at both congresses
- - New 12-month updates from JULIET trial of Kymriah® in relapsed/refractory DLBCL to be presented at EHA
- - Value of Novartis therapies treating lung and other cancers and blood disorders demonstrated in results of innovative health economic studies

EAST HANOVER, N.J., May 17, 2018 /PRNewswire/ -- Novartis will present data from across its oncology portfolio at the upcoming 54th Annual Meeting of the American Society of Clinical Oncology (ASCO) to be held June 1-5 in Chicago; and the 23rd Annual Congress of the European Hematology Association (EHA), scheduled for June 14-17 in Stockholm. With studies highlighting more than 25 compounds investigated in a range of disease areas including breast, renal cell and lung cancers, leukemias and other blood disorders, and myeloproliferative neoplasms (MPNs), the 84 abstracts that are part of the ASCO and EHA scientific programs illustrate the breadth and depth of Novartis' work in oncology.

"Novartis is improving the lives of people with cancer through a relentless commitment to scientific innovation," said Liz Barrett, CEO, Novartis Oncology. "Whether examining investigational treatment combinations, investigating treatment options that may redefine treatment goals of diseases like CML, or demonstrating the value of our therapies through real-world studies, Novartis continues to push boundaries as we reimagine cancer."

Novartis data at the 2018 ASCO Annual Meeting will highlight the following:

New data evaluating Kisqali® (ribociclib)* in broad range of patients with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2–) advanced breast cancer and additional update on investigational treatment, BYL719 (alpelisib):

- Ribociclib (RIB) + fulvestrant (FUL) in postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2–) advanced breast cancer (ABC): Results from MONALEESA-3 [Abstract #1000; Sunday, June 3, 8:00 AM CDT]
- Ribociclib (RIBO) + letrozole (LET) in patients (pts) with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced breast cancer (ABC) with no prior endocrine therapy (ET) for ABC: Preliminary results from the phase 3b CompLEEment-1 trial [Abstract #1056; Saturday, June 2, 8:00 AM CDT]
- Ribociclib (RIB) + tamoxifen (TAM) or a non-steroidal aromatase inhibitor (NSAI) in premenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2-) advanced breast cancer (ABC) who received prior chemotherapy (CT): MONALEESA-7 subgroup analysis [Abstract #1047; Saturday,

June 2, 8:00 AM CDT]

- First-line ribociclib (RIB) + letrozole (LET) in hormone receptor-positive (HR+), HER2-negative (HER2–) advanced breast cancer (ABC): MONALEESA-2 biomarker analyses [Abstract #1022; Saturday, June 2, 8:00 AM CDT]
- BYLieve: A phase II study of alpelisib (ALP) with fulvestrant (FUL) or letrozole (LET) for treatment of PIK3CA mutant, hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced breast cancer (aBC) progressing on/after cyclin-dependent kinase 4/6 inhibitor (CDK4/6i) therapy [Abstract #TPS1107; Saturday, June 2, 8:00 AM CDT]

Data evaluating real-world effectiveness and safety outcomes of first-line Votrient® (pazopanib) in patients with advanced renal cell carcinoma (RCC):

- Prospective, multinational, observational study of real-world treatment outcomes with pazopanib in patients with advanced or metastatic renal cell carcinoma (PRINCIPAL Study) [Abstract #4574; Saturday, June 2, 8:00 AM CDT]
- Comparison of clinical outcomes with first-line pazopanib in clinical trial eligible and non-clinical trial eligible patients with renal cell carcinoma [Abstract #4561; Saturday, June 2, 8:00 AM CDT]

New analyses of ENESTop and ENESTfreedom evaluating Treatment-free Remission (TFR) at 144-week follow-up after Tasigna® (nilotinib) treatment discontinuation in eligible adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in the chronic phase (Ph+ CML-CP):

- Long-term treatment-free remission (TFR) in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) after stopping second-line (2L) nilotinib: ENESTop 144-week results [Abstract #7003; Saturday, June 2, 4:00 PM CDT]
- Long-term treatment-free remission (TFR) following frontline (1L) nilotinib in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP): ENESTfreedom 144-wk results [Abstract #7063; Monday, June 4, 8:00 AM CDT]

Additional data presented at ASCO include:

- Trametinib in pediatric patients with neurofibromatosis type 1 (NF-1)–associated plexiform neurofibroma: A phase I/IIa study [Abstract #10504; Saturday, June 2, 4:12 PM CDT]
- Dabrafenib in pediatric patients with BRAF V600–positive high-grade glioma (HGG) [Abstract #10505; Saturday, June 2, 4:24 PM CDT]
- Efficacy and safety results from a phase I/IIa study of dabrafenib in pediatric patients with BRAF V600–mutant relapsed refractory low-grade glioma [Abstract #10506; Saturday, June 2, 4:36 PM CDT]
- Phase I/II study of spartalizumab (PDR001), an anti-PD1 mAb, in patients with anaplastic thyroid cancer [Abstract #6024; Saturday, June 2, 1:15 PM CDT]
- Phase I/II study of LAG525 ± spartalizumab (PDR001) in patients (pts) with advanced malignancies [Abstract #3012; Monday, June 4, 8:00 AM CDT]
- A phase I study of LXH254 in patients (pts) with advanced solid tumors harboring MAPK pathway alterations [Abstract #2586; Monday, June 4, 8:00 AM CDT]

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

- Comparison of efficacy and safety of biosimilar filgrastim in a randomized clinical trial (PIONEER) and real-world practice (MONITOR-GCSF) [Abstract #111; Monday, June 4, 10:21 AM CDT]

Advanced Accelerator Applications, a Novartis company and leader in nuclear medicine theragnostics, will

present an update on outcomes from the NETTER-1 study evaluating Lutathera® (lutetium Lu 177 dotatate) in patients with progressive midgut neuroendocrine tumors:

- First update on overall survival, progression-free survival, and health-related time-to-deterioration quality of life from the NETTER-1 study: 177Lu-Dotatate vs. high dose octreotide in progressive midgut neuroendocrine tumors [Abstract #4099; Sunday, June 3, 8:00 AM CDT]

Novartis data at the 2018 EHA Annual Congress will highlight the following:

Updates on outcomes with Kymriah® (tisagenlecleucel) in adult relapsed or refractory (r/r) patients with diffuse large b-cell lymphoma (DLBCL) and patient-reported quality of life in pediatric and young adult patients with r/r B-cell acute lymphoblastic leukemia (B-ALL)**:

- An updated analysis of JULIET, a global pivotal phase 2 trial of tisagenlecleucel in adult patients with relapsed or refractory (r/r) diffuse large b-cell lymphoma (DLBCL) [Abstract #S799; Saturday, June 16, 11:30 AM CEST]
- Outcomes of young adult patients (≥ 18-25 years) with relapsed/refractory (r/r) acute lymphoblastic leukemia (ALL) following treatment with chimeric antigen receptor (CAR) T-cell therapy [Abstract #S1565; Sunday, June 17, 8:00 AM CEST]
- Improvement of patient-reported quality of life following tisagenlecleucel infusion in pediatric and young adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia [Abstract #PF181; Friday, June 15, 5:30 PM CEST]
- Initial experience in US commercial manufacturing of tisagenlecleucel, a chimeric antigen receptor (CAR)-T cell therapy for pediatric relapsed/refractory B-cell precursor acute lymphoblastic leukemia [Abstract #PS1156; Saturday, June 16, 5:30 PM CEST]

New data evaluating Jakavi® (ruxolitinib)*** for patients with myelofibrosis, including those with early stage disease, and patients with polycythemia vera who are resistant to or intolerant of hydroxyurea:

- Comparison of ruxolitinib and real-world best available therapy in terms of overall survival and thrombosis in patients with polycythemia vera who are resistant or intolerant to hydroxyurea [Abstract #PF628; Friday, June 15, 5:30 PM CEST]
- Safety and efficacy of ruxolitinib (RUX) in patients (pts) with DIPSS low-risk myelofibrosis (MF) in the phase 3B expanded-access JUMP study [Abstract #PF623; Friday, June 15, 5:30 PM CEST]
- Predictors of response to ruxolitinib (RUX) in patients (pts) with myelofibrosis (MF) in the phase 3B expanded-access JUMP study [Abstract #PF616; Friday, June 15, 5:30 PM CEST]
- Results from 48-week follow-up of the EXPAND study: a phase 1b, open-label, dose-finding study of ruxolitinib in patients with myelofibrosis and low platelet counts (50-99 × 109/L) at baseline [Abstract #PF611; Friday, June 15, 5:30 PM CEST]

Further analyses of ENESTop and ENESTfreedom evaluating TFR at 144-week follow-up after Tasigna® (nilotinib) treatment discontinuation in eligible adult patients with Ph+ CML-CP:

- Long-term treatment-free remission (TFR) following second-line (2L) nilotinib (NIL) in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP): ENESTop 144-wk results [Abstract #PF377; Friday, June 15, 5:30 PM CEST]
- Long-term treatment-free remission (TFR) in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) following frontline (1L) nilotinib (NIL): Results from ENESTfreedom [Abstract #PF368; Friday, June 15, 5:30 PM CEST]

Safety analysis of the SUSTAIN study evaluating crizanlizumab in patients with sickle cell disease:

- Crizanlizumab treatment is not associated with the development of proteinuria and hematuria in patients with sickle cell disease: A safety analysis from the SUSTAIN study [Abstract #PF712; Friday, June 15, 5:30 PM CEST]

New data evaluating Revolade®/Promacta® (eltrombopag)**** in patients with either persistent or chronic immune thrombocytopenia (ITP):

- Eltrombopag treatment improved platelet counts in patients with persistent or chronic immune thrombocytopenia: Efficacy and safety results from the Phase III EXTEND study and a Phase IV study [Abstract #PF671; Friday, June 15, 5:30 PM CEST]

Interim results from the ITP World Impact Survey (I-WISh) about the burden of disease and impact of ITP on patient quality of life and productivity:

- The burden of disease and impact of Immune Thrombocytopenia (ITP) on patient quality of life and productivity: Results from the ITP World Impact Survey (I-WISh) [Abstract #PF654; Friday, June 15, 5:30 PM CEST]

Throughout the 2018 ASCO Annual Meeting and EHA Annual Congress, Novartis will host dedicated content on https://www.novartis.com/our-focus/cancer that will feature unique insights and perspectives on emerging areas of 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.novartis.com/our-company/global-product-portfolio.

For Lutathera® full prescribing information, including approved indications and important safety, please visit https://lutathera.com.

Alpelisib (BYL719), LAG525, spartalizumab (PDR001), LXH254 and crizanlizumab (SEG101) are investigational compounds. Efficacy and safety have not been established. There is no guarantee these compounds will become commercially available.

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," "expect," "anticipate," "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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality 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
Located in East Hanover, NJ Novartis Pharmaceuticals Corporation is an affiliate of Novartis which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 124,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://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.

** 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 for the investigational treatment of cancers.

*** 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.

**** Marketed as Promacta® in the United States and as Revolade® outside the United States.

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