Novartis data at ASCO, ICML and EHA meetings demonstrate meaningful advancements in cancer care

- **Updated analyses from the Kisqali® pivotal Phase III MONALEESA-2 trial in hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced breast cancer to be presented at ASCO**

- **JULIET trial of CTL019 (tisagenlecleucel) in relapsed/refractory diffuse large B-cell lymphoma (DLBCL) to be presented at ICML**

- **New data from the CTL019 ELIANA trial in pediatric and young adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL) at EHA**

- **New 96 week updates for Tasigna® Treatment-free Remission (TFR) trials evaluating Ph+ CML patients in both first-line setting and after switch from Glivec® at EHA**

**Basel, May 18, 2017** – Novartis will present data from across its oncology portfolio at the upcoming 53rd Annual Meeting of the American Society of Clinical Oncology (ASCO), being held June 2-6 in Chicago; the 14th International Conference on Malignant Lymphoma (ICML), being held June 14-17 in Lugano, Switzerland; and the 22nd Annual Congress of the European Hematology Association (EHA), being held June 22-25 in Madrid. With more than 75 abstracts accepted, data will highlight research across 34 compounds in key disease areas, including breast and lung cancers, melanoma, leukemia and other blood disorders, and myeloproliferative neoplasms (MPNs).

“Our presence at key medical congresses this year is marked by our innovation in targeted therapies and immuno-oncology in difficult to treat cancers,” said Bruno Strigini, CEO, Novartis Oncology. “We are particularly excited to show the first data from the JULIET trial, which evaluates the use of CTL019 in relapsed/refractory diffuse large B-cell lymphoma. These results, along with the data that led to our filing for CTL019 in relapsed/refractory pediatric and young adult patients with B-cell acute lymphoblastic leukemia, demonstrate our commitment to research in this area.”

**Novartis data at the 2017 ASCO Annual Meeting will highlight the following:**

**Update on outcomes with Kisqali® (ribociclib) in postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced breast cancer:**

- Updated Results from MONALEESA-2, a Phase 3 Trial of First-Line Ribociclib + Letrozole in Hormone Receptor-Positive (HR+), HER2-Negative (HER2−), Advanced Breast Cancer (ABC) [Abstract #1038; Sunday, June 4, 8:00 AM CDT]

- Health-Related Quality of Life (HRQoL) of Postmenopausal Women with Hormone Receptor-Positive (HR+), Human Epidermal Growth Factor Receptor 2-Negative (HER2-) Advanced Breast Cancer (ABC) Treated with Ribociclib + Letrozole: Results from MONALEESA-2 [Abstract #1020; Sunday, June 4, 8:00 AM CDT]
Data showing patient-reported quality of life outcomes for CTL019® (tisagenlecleucel), an investigational chimeric antigen receptor T cell (CAR-T) therapy, in relapsed/refractory pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL):

- Patient-Reported Quality of Life (QOL) Following CTL019 in Pediatric and Young Adult Patients (pts) with Relapsed/Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (B-ALL) [Abstract #10523; Sunday, June 4, 8:00 AM CDT]

New data evaluating long-term outcomes with Tafinlar® (dabrafenib) and Mekinist® (trametinib) combination therapy in patients with BRAF V600–mutated unresectable or metastatic melanoma as well as data from patients with other tumor types:

- Five-Year Overall Survival (OS) Update from a Phase II, Open-Label Trial of Dabrafenib (D) and Trametinib (T) in Patients (pts) with BRAF V600–Mutant Unresectable or Metastatic Melanoma (MM) [Abstract #9505; Sunday, June 4, 9:24 AM CDT]
- COMBI-MB: A Phase II Study of Combination Dabrafenib (D) and Trametinib (T) in Patients with BRAF V600–Mutant (mut) Melanoma Brain Metastases (MBM) [Abstract #9506; Sunday, June 4, 10:00 AM CDT]
- Updated Survival of Patients (pts) with Previously Treated BRAF V600E–Mutant Advanced Non-Small Cell Lung Cancer (NSCLC) who Received Dabrafenib (D) or D + Trametinib (T) in the Phase II BRF113928 Study [Abstract #9075; Saturday, June 3, 8:00 AM CDT]
- Efficacy of Dabrafenib (D) and Trametinib (T) in Patients (pts) with BRAF V600E–Mutated Anaplastic Thyroid Cancer (ATC) [Abstract #6023; Monday, June 5, 1:15 PM CDT]

New data on Zykdia® (ceritinib) as well as the investigational compound EGF816 which highlight continued investigations in the treatment of mutation-driven lung cancer:

- Ceritinib Plus Nivolumab (NIVO) in Patients (pts) with Anaplastic Lymphoma Kinase Positive (ALK+) Advanced Non-Small Cell Lung Cancer (NSCLC) [Abstract #2502; Saturday, June 3, 1:39 PM CDT]
- Genomic Profiling of Resistant Tumor Samples Following Progression on EGF816, a Third Generation, Mutant-Selective EGFR Tyrosine Kinase Inhibitor (TKI), in Advanced Non-Small Cell Lung Cancer (NSCLC) [Abstract #11506; Sunday, June 4, 9:48 AM CDT]

Adjuvant treatment of renal cell carcinoma (RCC) and safety and efficacy of combination therapy in treatment of advanced RCC:

- Randomized Phase III Trial of Adjuvant Pazopanib Versus Placebo After Nephrectomy in Patients with Locally Advanced Renal Cell Carcinoma (RCC) (PROTECT) [Abstract #4507; Monday, June 5, 10:12 AM CDT]
- A Phase I/II Study to Assess the Safety and Efficacy of Pazopanib (PAZ) and Pembrolizumab (PEM) in Patients (pts) with Advanced Renal Cell Carcinoma (aRCC) [Abstract #4506; Monday, June 5, 9:36 AM CDT]

Additional data presented at ASCO include:

- Phase III Study of Lapatinib (L) Plus Trastuzumab (T) and Aromatase Inhibitor (AI) vs T+AI vs L+AI in Postmenopausal Women (PMW) with HER2+, HR+ Metastatic Breast Cancer (MBC): ALTERNATIVE [Abstract #1004; Saturday, June 3, 2:27 PM CDT]
- Everolimus (EVE) Plus Endocrine Therapy in Patients with Estrogen Receptor–Positive (ER+), Human Epidermal Growth Factor Receptor 2–Negative (HER2−) Advanced Breast Cancer (BC): First and Second-Line Data from the BOLERO-4 Study [Abstract #1010; Sunday, June 4, 8:00 AM CDT]
• Cognitive Technology Addressing Optimal Cancer Clinical Trial Matching and Protocol Feasibility in a Community Cancer Practice [Abstract #6501; Monday, June 5, 8:12 AM CDT]

Sandoz, a Novartis division, the pioneer and global leader in biosimilars, will present data for Zarxio®, the company’s filgrastim biosimilar:
• Safety and Efficacy of Alternating Treatment with EP2006, a Filgrastim Biosimilar, and Reference Filgrastim for the Prevention of Severe Neutropenia, in Patients with Breast Cancer Receiving Myelosuppressive Chemotherapy [Abstract #10116; Saturday, June 3, 1:15 PM CDT]

Novartis data at the 14th Meeting of ICML will highlight data from the multi-center Phase II JULIET study evaluating the efficacy and safety of CTL019 in adult patients with r/r diffuse large B-cell lymphoma (DLBCL):
• Global Pivotal Phase 2 Trial of the CD19-Targeted Therapy CTL019 in Adult Patients with Relapsed or Refractory (R/R) Diffuse Large B-cell Lymphoma (DLBCL) – An Interim Analysis [Abstract #007; Wednesday, June 14, 3:40 PM CEST]

Novartis data at the 2017 EHA Annual Congress will highlight the following:

Data evaluating CTL019** outcomes in r/r pediatric and young adult patients with B-ALL:
• Global Registration Trial of Efficacy and Safety of CTL019 in Pediatric and Young Adult Patients with Relapsed/Refractory (R/R) Acute Lymphoblastic Leukemia (ALL): Update to the Interim Analysis [Abstract #S476; Saturday, June 24, 4:00 PM CEST]
• Analysis of Safety Data from 2 Multicenter Trials of CTL019 in Pediatric and Young Adult Patients with Relapsed/Refractory (R/R) B-Cell Acute Lymphoblastic Leukemia (B-ALL) [Abstract #P517; Saturday, June 24, 5:30 PM CEST]
• CTL019 Clinical Pharmacology and Biopharmaceutics in Pediatric Patients (pts) with Relapsed or Refractory (R/R) Acute Lymphoblastic Leukemia (ALL) [Abstract #S477; Saturday, June 24, 4:15 PM CEST]

New analyses of ENESTfreedom and ENEStop evaluating Treatment-free Remission (TFR) at 96-week follow-up in patients meeting rigorous criteria for treatment discontinuation:
• Durable Treatment-free Remission (TFR) After Stopping Second-line Nilotinib (NIL) in Patients (Pts) with Chronic Myeloid Leukemia in Chronic Phase (CML-CP): ENEStop 96-Wk Update [Abstract #P257; Friday, June 23, 5:15 PM CEST]
• Durable Treatment-free Remission (TFR) Following Frontline Nilotinib in Patients (Pts) with Chronic Myeloid Leukemia in Chronic Phase (CML-CP): ENESTfreedom 96-Wk Update [Abstract #P601; Saturday, June 24, 5:30 PM CEST]

Pooled survival analysis of two clinical trials evaluating Rydapt® (midostaurin) in adult patients with advanced systemic mastocytosis:
• Pooled Survival Analysis of Midostaurin Clinical Study Data (D2201 + A2213) in Patients with Advanced Systemic Mastocytosis (ADVSM) Compared with Historical Controls [Abstract #S788; Sunday, June 25, 9:00 AM CEST]

New data in myeloproliferative neoplasms, including a long-term analysis evaluating Jakavi® (ruxolitinib)*** in patients with inadequately controlled polycythemia vera in a less advanced phase of the disease:
• Ruxolitinib For The Treatment Of Inadequately Controlled Polycythemia Vera Without Splenomegaly: 80-Week Follow-Up From The RESPONSE-2 Trial [Abstract #S784; Sunday, June 25, 8:00 AM CEST]
• Comparing The Safety And Efficacy Of Ruxolitinib (Rux) In Patients (Pts) With DIPSS Low/Intermediate-1, Intermediate-2, And High-Risk Myelofibrosis (MF) In JUMP, A Phase 3b, Expanded-Access Study [Abstract #E1333; Friday, June 23, 9:30 AM CEST]
• Treatment and Management Of Patients With MPNs – Findings From the International MPN LANDMARK Survey [Abstract #P706; Saturday, June 24, 5:30 PM CEST]
• Perception Of Symptom Burden and Treatment Goals Between Physicians and Patients With MPNs: An Analysis From the International MPN LANDMARK Survey [Abstract #E1320; Friday, June 23, 9:30 AM CEST]

Additional data presented at EHA include:
• Mediation by Patient-Reported Outcomes on the Association Between Film-Coated versus Dispersible Formulations of Deferasirox and Serum Ferritin Reduction: A Post-Hoc Analysis of the ECLIPSE Trial [Abstract #P286; Friday, June 23, 5:15 PM CEST]
• Crizanlizumab, a P-selectin Inhibitor, Increases the Likelihood of Not Experiencing a Sickle Cell-Related Pain Crisis While on Treatment: Results from the Phase II SUSTAIN Study [Abstract #S454; Saturday, June 24, 12:15 PM CEST]

Throughout the 2017 ASCO Annual Meeting, ICML meeting and EHA Annual Meeting, Novartis Oncology will host dedicated content on the Novartis Oncology website (http://www.novartisoncology.com) 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.novartisoncology.com/news/product-portfolio.

EGF816, CTL019 and crizanlizumab (SEG101, formerly SelG1) are investigational compounds. Efficacy and safety have not been established. There is no guarantee these compounds will become commercially available.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “to be presented,” “will,” “upcoming,” “excited,” “commitment,” “invesigtational,” “emerging,” “yet,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Kisqali, Tasigna, Tafinlar, Mekinist, Zykdia, Afinitor, Zarxio, Rydapt, Jakavi or the other products in the Novartis Oncology portfolio, regarding potential marketing approvals for CTL019, EGF816, SEG101 or the other development compounds in the Novartis Oncology pipeline, or regarding potential future revenues from such products and development compounds. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Kisqali, Tasigna, Tafinlar, Mekinist, Zykdia, Afinitor, Zarxio, Rydapt, Jakavi or the other products in the Novartis Oncology portfolio will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that CTL019,
EGF816, SEG101 or the other development compounds in the Novartis Oncology pipeline will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that such products and development compounds will be commercially successful in the future. In particular, management’s expectations regarding such products and development compounds 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; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing and reimbursement pressures; safety, quality or manufacturing issues, 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 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 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 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.

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