Novartis to present pivotal data in hematologic and solid tumor cancers at 2016 ASCO Annual Meeting

- First data from two treatment-free remission (TFR) studies of Ph+ CML patients treated with Tasigna® both in front-line and second-line following Gleevec®

- First genomic analysis and 3-year efficacy/safety update for Tafinlar® + Mekinist® combination in BRAF V600E/K-mutant advanced melanoma, one of the most mature overall survival follow ups to date

- Data from open-label Phase II trial of investigational Tafinlar® and Mekinist® combination in previously-treated BRAF V600E–mutant advanced NSCLC

Basel, May 18, 2016 – Novartis will highlight the strength of its oncology research programs at the upcoming 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO), being held June 3-7 in Chicago. Data will demonstrate advances across several of the company’s core disease areas of focus including leukemias and lung, melanoma and breast cancers.

“We are particularly excited to share the results from the Tasigna Treatment-free Remission trials as these represent our unwavering commitment to further understand management approaches for Philadelphia chromosome-positive chronic myeloid leukemia,” said Bruno Strigini, President of Novartis Oncology. “These and other data at ASCO 2016 underscore our drive to advance cancer research for the benefit of patients.”

Novartis data at the 2016 ASCO Annual Meeting will highlight the following:

The potential for some patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), treated with Tasigna® (nilotinib), to achieve a sustained deep level of molecular response and maintain a major molecular response after stopping therapy – a concept called Treatment-free Remission (TFR):

- Treatment-free remission (TFR) in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) treated with frontline nilotinib: Results from the ENESTFreedom study [Abstract #7001; Saturday, June 4, 3:12 PM CDT]

- Treatment-free remission (TFR) in patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP) treated with second-line nilotinib (NIL): First results from the ENESTop study [Abstract #7054; Monday, June 6, 8:00 AM CDT]

Update on the efficacy and safety of Tafinlar® (dabrafenib) and Mekinist® (trametinib) combination therapy in patients with BRAF V600–mutated cancers, including potential indications under investigation:

- Genomic analysis and 3-y efficacy and safety update of COMBI-d: A Phase III study of dabrafenib (D) + trametinib (T) vs D monotherapy in patients with unresectable or metastatic BRAF V600E/K-mutant cutaneous melanoma [Abstract #9502; Monday, June 6, 1:39 PM CDT]
• An open-label Phase II trial of dabrafenib (D) in combination with trametinib (T) in patients with previously treated BRAF V600E–mutant advanced non-small cell lung cancer (NSCLC; BRF113928) [Abstract #107; Monday, June 6, 9:57 AM CDT]

• ROAR: A Phase II, open-label study in patients with BRAF V600E–mutated rare cancers to investigate the efficacy and safety of dabrafenib (D) and trametinib (T) combination therapy [Abstract # TPS2604; Sunday, June 5, 8:00 AM CDT]

**Update on CTL019, an investigational Chimeric Antigen Receptor T cell (CAR T) therapy, in relapsed/refractory pediatric acute lymphoblastic leukemia (ALL):**

• Sustained remissions with CD19-specific chimeric antigen receptor (CAR)-modified T cells in children with relapsed/refractory ALL [Abstract #3011; Monday, June 6, 4:54 PM CDT]

**Ongoing investigation of established and pipeline therapies for patients with unmet needs:**

• Long-term outcomes of ruxolitinib (RUX) therapy in patients with myelofibrosis (MF): 5-year update from COMFORT-I [Abstract #7012; Monday, June 6, 11:30 AM CDT]**

• Phase I study of the safety and efficacy of the cMET inhibitor capmatinib (INC280) in patients (pts) with advanced cMET+ non-small cell lung cancer (NSCLC) [Abstract #9067; Saturday, June 4, 8:00 AM CDT]

Additional notable data from Novartis’ core disease areas of focus include:

**Breast Cancer:**

• A randomized trial (MA.17R) of extending adjuvant letrozole for 5 years after completing an initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen in postmenopausal women with early-stage breast cancer [Abstract #LBA1; Sunday, June 5, 1:40 PM CDT]

• Patient-reported outcomes from MA.17R: A randomized trial of extending adjuvant letrozole for 5 years after completing an initial 5 years of aromatase inhibitor therapy alone or preceded by tamoxifen in postmenopausal women with early-stage breast cancer [Abstract #LBA506; Monday, June 6, 3:15 PM CDT]

• Correlation of PIK3CA mutations in cell-free DNA (cfDNA) and efficacy of everolimus (EVE) in metastatic breast cancer: Results from BOLERO-2 [Abstract #519; Sunday, June 5, 11:30 AM CDT]

• Prevention of everolimus/exemestane (EVE/EXE) stomatitis in postmenopausal (PM) women with hormone receptor-positive (HR+) metastatic breast cancer (MBC) using a dexamethasone-based mouthwash (MW): Results of the SWISH trial [Abstract #525; Sunday, June 5, 8:00 AM CDT]

• Evaluation of lapatinib as a component of neoadjuvant therapy for HER2+ operable breast cancer: 5-year outcomes of NSABP protocol B-41 [Abstract #501; Monday, June 6, 1:27 PM CDT]

• Ribociclib (LEE011) and letrozole in estrogen receptor-positive (ER+), HER2-negative (HER2−) advanced breast cancer (aBC): Phase Ib safety, preliminary efficacy and molecular analysis [Abstract #568; Sunday, June 5, 8:00 AM CDT]

**Lung Cancer:**

• Genetic landscape of ALK+ non-small cell lung cancer (NSCLC) patients and response to ceritinib in ASCEND-1 [Abstract #9064; Saturday, June 4, 8:00 AM CDT]

• Phase II safety and efficacy results of a single-arm Ph Ib/II study of capmatinib (INC280) + gefitinib in patients with EGFR-mutated (mut), cMET-positive (cMET+) non-small cell lung cancer (NSCLC) [Abstract #9020; Saturday, June 4, 3:00 PM CDT]
Hematology:
- PILLAR-2: A randomized, double-blind, placebo-controlled, Phase III study of adjuvant everolimus (EVE) in patients (pts) with poor-risk diffuse large B-cell lymphoma (DLBCL) [Abstract #7506; Sunday, June 5, 11:45 AM CDT]
- ReTHINK: A randomized, double-blind, placebo-controlled, multicenter, Phase III study of ruxolitinib in early myelofibrosis patients [Abstract #TPS7080; Monday, June 6, 8:00 AM CDT]**
- Patient reported outcomes (PROs) of multiple myeloma (MM) patients treated with panobinostat (PAN) after ≥2 lines of therapy based on the international Phase III, randomized, double-blind, placebo-controlled, PANORAMA-1 trial [Abstract #8054; Monday, June 6, 8:00 AM CDT]

Other Tumor Types:
- A first-in-human phase I study of the anti-PD-1 antibody PDR001 in patients with advanced solid tumors [Abstract #3060; Sunday, June 5, 8:00 AM CDT]
- BERIL-1: A Phase II, placebo-controlled study of buparlisib (BKM120) plus paclitaxel vs placebo plus paclitaxel in patients with platinum-pretreated recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) [Abstract #6008; Sunday, June 5, 10:12 AM CDT]
- BERIL-1: Biomarker results from targeted sequencing of circulating tumor DNA (ctDNA) and archival tissue in a randomized Phase II study of buparlisib (BKM120) or placebo + paclitaxel in patients with head and neck squamous cell carcinoma (HNSCC) [Abstract #6045; Saturday, June 4, 1:00 PM CDT]
- A Phase II study of the efficacy and safety of the cMET inhibitor capmatinib (INC280) in patients (pts) with advanced hepatocellular carcinoma (HCC) [Abstract #4074; Saturday, June 4, 8:00 AM CDT]
- Everolimus (EVE) in advanced, nonfunctional, well-differentiated neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin: Second interim overall survival (OS) results from the RADIANT-4 study [Abstract #4090; Saturday, June 4, 8:00 AM CDT]
- Genomic mutation profiling (GMP) and clinical outcome in patients (pts) treated with ribociclib (CDK4/6 inhibitor) in the Signature program [Abstract 2528; Sunday, June 5, 8:00 AM CDT]

Throughout the 2016 ASCO Annual Meeting, Novartis Oncology will host dedicated content on the company 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.

Because INC280, CTL019, LEE011, BKM120 and PDR001 are investigational compounds, the safety and efficacy profiles have not yet been fully established. Access to these investigational compounds is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that INC280, CTL019, LEE011, BKM120 and PDR001 will ever be commercially available anywhere in the world.
Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "to present," "investigational," "will," "upcoming," "excited," "commitment," "drive," "potential," "ongoing," "pipeline," "emerging," "yet," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Tafinlar (dabrafenib) and Mekinist (trametinib) combination therapy, Tasigna (nilotinib), Gleevec (imatinib), Femara (letrozole), everolimus, Tykerb (lapatinib), Zykdia (ceritinib), Farydak (panobinostat) and Jakavi (ruxolitinib), regarding potential marketing approvals for BKM120, PDR001, CTL019, INC280 and LEE011 or regarding potential future revenues from such products and development projects. 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 any of Tafinlar and Mekinist combination therapy, Tasigna, Gleevec, Femara, everolimus, Tykerb, Zykdia, Farydak or Jakavi 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 any of BKM120, PDR001, CTL019, INC280 or LEE011 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that such products and development projects will be commercially successful in the future. In particular, management's expectations regarding such products and development projects could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected 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 pressures; unexpected safety issues; unexpected manufacturing or quality 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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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

*Known as Gleevec® (imatinib mesylate) tablets in the US, Canada and Israel.

**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

Central media line : +41 61 324 2200
Eric Althoff
Novartis Global Media Relations

Rosemarie Yancosek
Novartis Oncology
+41 61 324 7999 (direct) +1 862-778-9043 (direct)
+41 79 593 4202 (mobile) +1 862-505-9021 (mobile)
eric.althoff@novartis.com rosemarie.yancosek@novartis.com
e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone: +41 61 324 7944
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065 Richard Pulik +1 212 830 2448
Thomas Hungerbuehler +41 61 324 8425 Sloan Pavsner +1 212 830 2417
Isabella Zinck +41 61 324 7188

e-mail: investor.relations@novartis.com e-mail: investor.relations@novartis.com