Novartis data at ASH and SABCS showcase latest innovations in development for patients with blood disorders and breast cancer

- First results from global registrational trial of CAR T therapy, CTL019, in pediatric relapsed/refractory acute lymphoblastic leukemia

- Sub-group analyses from pivotal MONALEESA-2 trial of LEE011 (ribociclib) plus letrozole in women with HR+/HER2- advanced breast cancer

- Post-hoc analysis of Tasigna® (nilotinib) treatment-free remission rates in patients who switched from imatinib due to intolerance, resistance or physician preference

Basel, November 16, 2016 – Novartis will present data demonstrating the latest advancements from its oncology research program at the 58th American Society of Hematology (ASH) Annual Meeting & Exposition, San Diego, December 3-6, and the San Antonio Breast Cancer Symposium (SABCS), San Antonio, December 6-10. Presentations will focus on a number of cancers, including leukemia, lymphoma, myelofibrosis and breast cancer, as well as chronic iron overload. The data reinforce Novartis’ dedication to developing transformative therapies and treatment strategies to improve and extend the lives of people living with these diseases.

“Novartis continues to invest in not only creating new medicines for underserved patient communities, but also in redefining cancer treatment goals,” said Bruno Strigini, CEO, Novartis Oncology. “Our ASH and SABCS data, including personalized cell and targeted therapies of the future, underscore our core belief in treating each patient as an individual, not just the disease."

Most notable among Novartis’ clinical data to be featured at the two meetings are from the ongoing registrational trials for investigational CTL019* and LEE011** (ribociclib). The CTL019 data will be included in upcoming regulatory submissions. Novartis also recently received US Food and Drug Administration Priority Review for LEE011 (ribociclib) plus letrozole as first-line treatment for postmenopausal women with HR+/HER2- advanced or metastatic breast cancer, based on results from the MONALEESA-2 study.

- Analysis of a Global Registration Trial of the Efficacy and Safety of CTL019 in Pediatric and Young Adults with Relapsed/Refractory Acute Lymphoblastic Leukemia (ALL) (Abstract #221, Oral Presentation, Saturday, December 3, 5:00 pm PST)

- First-Line Ribociclib Plus Letrozole in Patients with De Novo HR+/HER2- Advanced Breast Cancer (ABC): A Subgroup Analysis of the MONALEESA-2 Trial (Abstract #P4-22-05, Poster Presentation, Friday, December 9, 7:30 – 9:00 am CST)

- First-Line Ribociclib Plus Letrozole in Patients with HR+/HER2- Advanced Breast Cancer (ABC) Presenting with Liver and/or Lung Metastases or Bone-Only Disease: A Subgroup Analysis of the MONALEESA-2 trial (Abstract #P4-22-16, Poster Presentation, Friday, December 9, 7:30 – 9:00 am CST)

Novartis will also be presenting safety, efficacy and quality of life data at ASH from its hematology portfolio, including an investigational use for Tasigna® (nilotinib). Five-year pooled overall survival data for Jakavi® (ruxolitinib)*** in patients with myelofibrosis and patient-
reported health-related outcomes from patients with chronic immune thrombocytopenia taking Revołade® (eltrombopag)** will also be presented.

- Treatment-Free Remission in Patients with Chronic Myeloid Leukemia in Chronic Phase According to Reasons for Switching from Imatinib to Nilotinib: Subgroup Analysis from ENESTop (Abstract #792, Oral Presentation, Monday, December 5, 11:45 am PST)
- A Pooled Overall Survival Analysis of 5-Year Data from the COMFORT-I and COMFORT-II Trials of Ruxolitinib for the Treatment of Myelofibrosis (Abstract #3110, Poster Presentation, Sunday, December 4, 6:00 – 8:00 pm PST)
- The Impact of Myeloproliferative Neoplasms (MPNs) on Patients’ Quality of Life and Productivity: Results from the International MPN LANDMARK Survey (Abstract #4267, Poster Presentation, Monday, December 5, 6:00 – 8:00 pm PST)
- Patient-Reported Health-Related Quality of Life Improves Over Time in Patients with Chronic Immune Thrombocytopenia Receiving Long-Term Treatment with Eltrombopag (Abstract #3750, Poster Presentation, Monday, December 5, 6:00 – 8:00 pm PST)

Sandoz, a Novartis division, the pioneer and global leader in biosimilars, will present pivotal Phase III safety and efficacy data for its proposed biosimilar rituximab.

- A Phase III Efficacy and Safety Study of the Proposed Rituximab Biosimilar GP2013 versus Rituximab in Patients with Previously Untreated Advanced Follicular Lymphoma (Abstract #1809, Poster Presentation, Saturday, December 3, 5:30 – 7:30 pm PST)

Additional abstracts of note from each meeting are as follows.

**ASH: Data for investigational therapies**

**ABL001**

- Expanded Phase I Study Update of ABL001, a Potent, Allosteric Inhibitor of BCR-ABL, Reveals Significant and Durable Responses in Patients with CML-Chronic Phase with Failure of Prior TKI Therapy (Abstract #625, Oral Presentation, Monday, December 5, 7:00 am PST)

**CTL019**

- Efficacy and Safety of CTL019 in the First US Phase II Multicenter Trial in Pediatric Relapsed/Refractory Acute Lymphoblastic Leukemia: Results of an Interim Analysis (Abstract #2801, Poster Presentation, Sunday, December 4, 6:00 – 8:00 pm PST)
- Treatment with Chimeric Antigen Receptor Modified T Cells Directed Against CD19 (CTL019) Results in Durable Remissions in Patients with Relapsed or Refractory Diffuse Large B Cell Lymphomas of Germinal Center and Non-Germinal Center Origin, “Double Hit” Diffuse Large B Cell Lymphomas, and Transformed Follicular to Diffuse Large B Cell Lymphomas (Abstract #3026, Poster Presentation, Sunday, December 4, 6:00 – 8:00 pm PST)

**PKC412 (midostaurin)**

- Radius: A Phase II, Randomized Trial of Standard of Care (SOC) with or without Midostaurin to Prevent Relapse Following Allogeneic Hematopoietic Stem Cell Transplantation in Patients with FLT3-ITD Mutated Acute Myeloid Leukemia (Abstract #2248, Poster Presentation, Saturday, December 3, 5:30 – 7:30 pm PST)

**ASH: Data for approved therapies**

*Exjade®/Jadenu™* (deferasirox)
• Improved Patient-Reported Outcomes with a Film-Coated Versus Dispersible Tablet Formulation of Deferasirox: Results from the Randomized, Phase II ECLIPSE Study (Abstract #850, Oral Presentation, Monday, December 5, 3:30 pm PST)
• New Film-Coated Tablet Formulation of Deferasirox is Well Tolerated in Patients with Thalassemia or MDS: Results of the Randomized, Phase II ECLIPSE Study (Abstract #1285, Poster Presentation, Saturday, December 3, 5:30 – 7:30 pm PST)

Jakavi® (ruxolitinib)
• Effects of Long-Term Ruxolitinib (RUX) on Bone Marrow (BM) Morphology in Patients with Myelofibrosis (MF) Enrolled in the COMFORT-I Study (Abstract #1949, Poster Presentation, Saturday, December 3, 5:30 – 7:30 pm PST)
• Safety and Efficacy of Ruxolitinib for the Final Enrollment of JUMP: An Open-Label, Multicenter, Single-Arm, Expanded-Access Study in Patients with Myelofibrosis (N = 2233) (Abstract #3107, Poster Presentation, Sunday, December 4, 6:00 – 8:00 pm PST)

ASH: Investigational use of approved therapies

Revolade®/Promacta® (eltrombopag)
• Thrombopoietin (TPO) Receptor Agonist Eltrombopag in Combination with Azacitidine (AZA) for Primary Treatment of Myelodysplastic Syndromes (MDS) Patients with Thrombocytopenia: Outcomes from the Randomized, Placebo-Controlled, Phase III SUPPORT Study (Abstract #163, Oral Presentation, Saturday, December 3, 2:00 pm PST)

Tasigna® (nilotinib)
• ENESTPath: A Phase III Study to Assess the Effect of Nilotinib Treatment Duration on Treatment-Free Remission (TFR) in Patients with Chronic Phase-Chronic Myeloid Leukemia Previously Treated with Imatinib: 24-Month Analysis of the First 300 Patients in the Induction/Consolidation Phase (Abstract #3094, Poster Presentation, Sunday, December 4, 6:00 – 8:00 pm PST)

SABCS: Data for investigational therapies

LEE011 (ribociclib)
• Ribociclib + Fulvestrant in Postmenopausal Women with HR+/HER2- Advanced Breast Cancer (ABC) (Abstract #P4-22-12, Poster Presentation, Friday, December 9, 7:30 – 9:00 am CST)
• Phase Ib Safety, Efficacy and Molecular Analysis of Ribociclib (LEE011) plus Letrozole for the Treatment of ER+/HER2- Advanced Breast Cancer (Abstract #P4-22-18, Poster Presentation, Friday, December 9, 7:30 – 9:00 am CST)

BKM120 (buparlisib)
• BELLE-3: A Phase III Study of Buparlisib + Fulvestrant in Postmenopausal Women with HR+/HER2-, aromatase Inhibitor-Treated, Locally Advanced or Metastatic Breast Cancer, who Progressed on or after mTOR Inhibitor-Based Treatment (Abstract #S4-07, Oral Presentation, Thursday, December 8, 4:45 pm CST)

SABCS: Investigational use of approved therapies

Afinitor® (everolimus)
• PrECOG 0102: A Randomized, Double-Blind, Phase II Trial of Fulvestrant Plus Everolimus or Placebo in Postmenopausal Women with Hormone Receptor (HR)-Positive, HER2-Negative Metastatic Breast Cancer (MBC) Resistant to Aromatase Inhibitor (AI) Therapy (Designed and conducted independently by PrECOG, LLC with
partial support from Novartis) (Abstract S1-02, Oral Presentation, Wednesday, December 7, 9:00 am CST)

Novartis Oncology will host dedicated content on the company website (http://www.novartisoncology.com) throughout ASH and SABCS, featuring unique insights and perspectives on emerging areas of cancer care and research. Additionally, follow @NovartisCancer on Twitter for the latest oncology news and insights on cancer 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 the compounds will become commercially available with additional indications.

For full prescribing information, including approved indications and important safety information about globally marketed products, please visit https://www.novartisoncology.com/our-work/product-portfolio.

Because CTL019, LEE011 (ribociclib), ABL001, PKC412 (midostaurin) and BKM120 (buparlisib) 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 compounds. Because of the uncertainty of clinical trials, there is no guarantee that CTL019, LEE011 (ribociclib), ABL001, PKC412 (midostaurin) and BKM120 (buparlisib) will ever become commercially available anywhere in the world.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "will," "dedication," "continues to invest," "therapies of the future," "to be featured," "ongoing," "investigational," "upcoming," "emerging," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Tasigna, Jakavi, Promacta, Revolade, Exjade, Jadenu and Afinitor, potential marketing approvals for CTL019, LEE011, ABL001, PKC412 and BKM120, or regarding potential future revenues from such products and investigational 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 Tasigna, Jakavi, Promacta, Revolade, Exjade, Jadenu or Afinitor 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, LEE011, ABL001, PKC412 or BKM120 will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that such products and investigational compounds will be commercially successful in the future. In particular, management's expectations regarding these products and investigational compounds 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, 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, 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 approximately 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 and @NovartisCancer at http://twitter.com/novartiscancer. 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

* Novartis and the University of Pennsylvania's Perelman School of Medicine (Penn) have a global collaboration to research, develop and commercialize chimeric antigen receptor (CAR) T cell therapies for the investigational treatment of cancers.

** LEE011 was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

*** 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 US.

###

Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Rosemarie Yancosek
Novartis Oncology
+ 1 862 778 9043 (direct)
+ 1 862 505 9021 (mobile)
rosemarie.yancosek@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Sloan Pavsner +1 212 830 2417