Novartis highlights clinical advances at ASH 2015, underscoring leadership in hematology research

- Pivotal overall survival data for investigational compound PKC412 (midostaurin) in adults with newly diagnosed FLT3-mutated acute myeloid leukemia
- Presentations highlight new CTL019 data in relapsed/refractory ALL and NHL and successful transfer of cell processing technology to Novartis
- Results from PROTECT 2, from Sandoz, investigating use of proposed biosimilar pegfilgrastim in patients with chemotherapy-induced neutropenia

Basel, November 30, 2015 – Novartis will demonstrate the strength of its research program and portfolio at the 57th American Society of Hematology (ASH) Annual Meeting. Presentations will highlight data across leukemias, lymphomas and myelomas as well as supportive care, including key findings in rare and difficult-to-treat patient populations, in addition to personalized cell therapies. The ASH Annual Meeting will be held December 5-8 in Orlando, Florida.

“We pride ourselves in our drive for new science and innovation, and look forward to bringing this promise to life at ASH through the results of our latest hematology research,” said Bruno Strigini, President, Novartis Oncology. “We will be presenting encouraging overall survival data for both investigational and approved products, underscoring our commitment to improve and extend people’s lives.”

A key focus in hematology for Novartis is developing therapies for rare and difficult-to-treat patient populations. The acute myeloid leukemia (AML) community in particular is in need of new treatment options as the general therapeutic strategy has remained unchanged for more than 25 years.1,2 Further, about one-third of AML patients harbor a FLT3 mutation, which is associated with poorer prognoses than in those without the mutation3,4. To this end, key data on PKC412 (midostaurin) from the following two studies will be presented:

- The Multi-Kinase Inhibitor Midostaurin (M) Prolongs Survival Compared with Placebo (P) in Combination with Daunorubicin (D)/Cytarabine (C) Induction (ind), High-Dose C Consolidation (consol), and As Maintenance (maint) Therapy in Newly Diagnosed Acute Myeloid Leukemia (AML) Patients (pts) Age 18-60 with FLT3 Mutations (muts): An International Prospective Randomized (rand) P-Controlled Double-Blind Trial (CALGB 10603/RATIFY [Alliance]) (Abstract #6, Plenary Session, Sunday, December 6, 2:00 – 4:00 pm EST)
- Midostaurin in Combination with Intensive Induction and As Single Agent Maintenance Therapy after Consolidation Therapy with Allogeneic Hematopoietic Stem Cell Transplantation or High-Dose Cytarabine (NCT01477606) (Abstract #322, Oral Presentation, Sunday, December 6, 5:15 pm EST)

Novartis and the University of Pennsylvania’s Perelman School of Medicine (Penn) have an exclusive global collaboration to research, develop and commercialize chimeric antigen receptor (CAR) T cell therapies for the investigational treatment of cancers. New
data on investigational CART therapy CTL019, as well as cell processing technology will be presented at ASH including:

- **Durable Remissions in Children with Relapsed/Refractory ALL Treated with T Cells Engineered with a CD19-Targeted Chimeric Antigen Receptor (CTL019)** (Abstract #681, Oral Presentation, Monday, December 7, 3:15 pm EST)
- **Sustained Remissions Following Chimeric Antigen Receptor Modified T Cells Directed Against CD19 (CTL019) in Patients with Relapsed or Refractory CD19+ Lymphomas** (Abstract #183, Oral Presentation, Sunday, December 6, 8:00 am EST)
- **Successful Translation of Chimeric Antigen Receptor (CAR) Targeting CD19 (CTL019) Cell Processing Technology from Academia to Industry** (Abstract #3100, Poster Presentation, Sunday, December 6, 6:00 – 8:00 pm EST)

Novartis will share new research for pipeline compound ABL001, a small molecule designed to inhibit BCR-ABL. ABL001 is different from Glivec® (imatinib)* and Tasigna® (nilotinib) as it binds to a unique region of BCR-ABL, forcing a conformational change that disables the protein’s active site. As part of Novartis’ ongoing commitment to chronic myeloid leukemia (CML) research, ABL001 represents the company’s evolving science and is being investigated in Phase I trials:

- ABL001, a Potent, Allosteric Inhibitor of BCR-ABL, Exhibits Safety and Promising Single-Agent Activity in a Phase I Study of Patients with CML with Failure of Prior TKI Therapy (Abstract #138, Oral Presentation, Saturday, December 5, 5:15 pm EST)

Novartis will also be presenting safety and efficacy data, including long-term studies, at ASH from its approved hematological treatments:

**Jakavi® (ruxolitinib)**

- Long-Term Efficacy and Safety in COMFORT-II, a Phase 3 Study Comparing Ruxolitinib with Best Available Therapy for the Treatment of Myelofibrosis: 5-Year Final Study Results (Abstract #59, Oral Presentation, Saturday, December 5, 10:30 am EST)
- Safety and Efficacy of Ruxolitinib in an 1869-Patient Cohort of JUMP: An Open-Label, Multicenter, Single-Arm, Expanded-Access Study in Patients with Myelofibrosis (Abstract #2799, Poster Presentation, Sunday, December 6, 6:00 – 8:00 pm EST)
- Demographics, Baseline (BL) Characteristics, and Disease Symptom Burden in RESPONSE-2: A Randomized, Phase 3 Study of Ruxolitinib in Polycythemia Vera Patients (pts) Who Are Resistant to or Intolerant of Hydroxyurea (HU) (Abstract #2807, Poster Presentation, Sunday, December 6, 6:00 – 8:00 pm EST)
- Continued Treatment With Ruxolitinib Provides Additional Hematocrit Control and Spleen Volume Responses in Patients with PV Treated in the RESPONSE Study (Abstract #2804, Poster Presentation, Sunday, December 6, 6:00 – 8:00 pm EST)

**Tasigna (nilotinib)**

- Dose-Optimized Nilotinib (NIL) in Patients (pts) with Newly Diagnosed Chronic Myeloid Leukemia in Chronic Phase (CML-CP): Final results from ENESTxtnd study (Abstract #344, Oral Presentation, Sunday, December 6, 4:45 pm EST)
- Impact of Age on Efficacy and Toxicity of Nilotinib in Patients with Chronic Myeloid Leukemia in Chronic Phase (CML-CP): ENEST1st Sub-Analysis (Abstract #479, Oral Presentation, Monday, December 7, 8:00 am EST)
- International Scale (IS)-Standardized BCR-ABL1 Digital Polymerase Chain Reaction (dPCR) Assays Using ABL1, BCR, and GUS Control Genes for Measuring Deep Molecular Response (MR) in Chronic Myeloid Leukemia (CML) (Abstract #136, Oral Presentation, Saturday, December 5, 4:45 pm EST)
- Quantification of BCR-ABL with Digital PCR Results in a Significantly Lower Rate of Deep Molecular Response when Compared to RT-qPCR in CML Patients
Treated in the ENEST1st Trial (Abstract #135, Oral Presentation, Saturday, December 5, 4:30 pm EST)

**Farydak® (panobinostat)**
- Final Analysis of Overall Survival from the Phase 3 Panorama 1 Trial of Panobinostat Plus Bortezomib and Dexamethasone Versus Placebo Plus Bortezomib and Dexamethasone in Patients with Relapsed or Relapsed and Refractory Multiple Myeloma (Abstract #3026, Poster Presentation, Sunday, December 6, 6:00 – 8:00 pm EST)
- Analysis of Outcomes Based on Response in Patients with Relapsed or Relapsed and Refractory Multiple Myeloma Treated with Panobinostat or Placebo in Combination with Bortezomib and Dexamethasone in the Panorama 1 Trial: Updated Analysis Based on Prior Treatment (Abstract #4230, Poster Presentation, Monday, December 7, 6:00 – 8:00 pm EST)

In addition, Sandoz, a Novartis company and the global leader in biosimilars, will present data from PROTECT 2, one of their pivotal Phase III trials investigating use of their proposed pegfilgrastim biosimilar in patients with chemotherapy-induced neutropenia.
- Proposed Biosimilar Pegfilgrastim (LA-EP2006) and Reference Pegfilgrastim for the Prevention of Neutropenia in Patients with Breast Cancer: A Randomized, Double-Blind Trial. PROTECT 2: Pegfilgrastim Randomized Oncology (supportive care) Trial to Evaluate Comparative Treatment Results (Abstract #632, Oral Presentation, Monday, December 7, 10:45 am EST)

Throughout ASH 2015, Novartis Oncology will host dedicated content on the company website [http://www.novartisoncology.com](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/our-work/product-portfolio](https://www.novartisoncology.com/our-work/product-portfolio).

Because PKC412 (midostaurin), CTL019 and ABL001 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 PKC412 (midostaurin), CTL019 and ABL001 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 “investigational,” “investigating,” “proposed,” “will,” “drive,” “look forward,” “promise,” “encouraging,” “commitment,” “focus,” “being investigated,” “yet,” or similar terms, or by express or implied discussions regarding potential marketing approvals for PKC412, CTL019, ABL001 or proposed biosimilar pegfilgrastim, or regarding potential new indications or labeling for Glivec, Tasigna, Jakavi or Farydak, 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 PKC412, CTL019, ABL001 or proposed biosimilar pegfilgrastim will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Glivec, Tasigna, Jakavi or Farydak will be submitted or approved for any additional indications or labeling 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 such 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 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 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 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.

*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.

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For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
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