Novartis features innovative immunotherapy, targeted pipeline treatment combinations and long-term data at ASH and SABCS 2014

- Update on complete remissions with personalized cell therapy CTL019 in patients with relapsed/refractory acute lymphoblastic leukemia
- Studies targeting multiple cancer pathways in rare blood cancer myelofibrosis exploring combinations of Jakavi® with LBH589, BKM120 or LDE225
- Long-term data on safety and efficacy in key hematological treatments Tasigna®, Jakavi® and Exjade® in large patient cohorts
- Updates on advanced breast cancer portfolio at SABCS, including Afinitor® and pipeline compounds targeting PI3K/AKT/mTOR and CDK 4/6 pathways

Basel, December 2, 2014 – Novartis will highlight more than 250 abstracts demonstrating advances in blood and breast cancer research at the upcoming American Society of Hematology (ASH) annual meeting December 6-9, and CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) December 9-13. Presentations will highlight cell and gene therapy research, approaches to targeting multiple pathways at once to treat various cancers and established safety and efficacy with long-term data from the hematology portfolio.

"Novartis continues to pioneer innovative therapies across our broad and diverse portfolio as we work to improve the lives of patients living with cancer. At ASH and SABCS, we’ll share long-term safety and efficacy data on several targeted therapies and present findings on novel treatment approaches including pipeline combinations and personalized cell therapy," said Alessandro Riva, MD, Global Head, Novartis Oncology Development and Medical Affairs. "As ASH begins, we are reminded of how far we’ve come since the unprecedented Glivec data unveiled exactly 15 years ago – a turning point in precision oncology. With our robust cancer pipeline, we look forward to many more years of meaningful progress for people living with cancer."

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

- T Cells Engineered with a Chimeric Antigen Receptor (CAR) Targeting CD19 (CTL019) Have Long Term Persistence and Induce Durable Remissions in Children with Relapsed, Refractory ALL (ASH Abstract #380; December 8, 10:45 AM PST)

*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.
• Phase IIa Trial of Chimeric Antigen Receptor Modified T Cells Directed Against CD19 (CTL019) in Patients with Relapsed or Refractory CD19+ Lymphomas (ASH Abstract #3087; December 7, 6:00 PM PST)

• Refractory Cytokine Release Syndrome in Recipients of Chimeric Antigen Receptor (CAR) T Cells (ASH Abstract #2296; December 7, 6:00 PM PST)

• Randomized, Phase II Dose Optimization Study of Chimeric Antigen Receptor Modified T Cells Directed Against CD19 (CTL019) in Patients with Relapsed, Refractory CLL (ASH Abstract #1982; December 6, 5:30 PM PST)

Combination therapy to simultaneously target multiple cancer pathways is another research focus for Novartis, with data presented at ASH exploring combination strategies across a range of hematological cancers, including:

• Efficacy and Safety Based on Duration of Treatment of Panobinostat plus Bortezomib and Dexamethasone in Patients with Relapsed or Relapsed and Refractory Multiple Myeloma in the Phase III PANORAMA 1 Study (ASH Abstract #4742; December 8, 6:00 PM PST)

• Efficacy, Safety, and Confirmation of the Recommended Phase II Dose of Ruxolitinib Plus Panobinostat in Patients With Intermediate or High-Risk Myelofibrosis (ASH Abstract #711; December 8, 6:45 PM PST)

• HARMONY: An Open-Label, Multicenter, 2-arm, Dose-Finding Phase Ib Study of the Combination of Ruxolitinib and Buparlisib (BKM120) in Patients With Myelofibrosis (MF) (ASH Abstract #710; December 8, 6:30 PM PST)

• Phase Ib Dose-Escalation Study of Sonidegib (LDE225) in Combination With Ruxolitinib (INC424) in Patients With Myelofibrosis (ASH Abstract #712; December 8, 7:00 PM PST)

Data from new combination strategies presented at SABCS includes the latest findings on Afinitor® (everolimus) in HR+ and HER2+ advanced or metastatic breast cancer:

• Subgroup analysis on efficacy in the routine treatment - Results of the 2nd interim analysis of BRAWO, the non-interventional trial “Breast Cancer Treatment with Everolimus and Exemestane for HR+ Women” (SABCS Abstract # P5-19-12; December 12, 5:00 PM CDT)

• Everolimus in combination with exemestane in hormone receptor-positive locally advanced or metastatic breast cancer patients progressing on prior non-steroidal AI (NSAIs): Ballet study (CRAD001YIC04) (SABCS Abstract # P5-19-02; December 12, 5:00 PM CDT)

• Phase III, randomized, double-blind, placebo-controlled multicenter trial of daily everolimus plus weekly trastuzumab and paclitaxel as first-line therapy in women with HER2+ advanced breast cancer: BOLERO-1 (SABCS Abstract #S6-01; December 12, 3:15 PM CDT)

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

• Efficacy and Safety of Nilotinib (NIL) vs Imatinib (IM) in Patients With Newly Diagnosed Chronic Myeloid Leukemia in Chronic Phase: Long-Term Follow-Up of ENESTnd (ASH Abstract #4541; December 8, 6:00 PM PST)

• Relationship Between Chelation and Clinical Outcomes in Lower-Risk Patients With Myelodysplastic Syndrome: Registry Analysis at 5 Years (US CPO) (ASH Abstract #1350; December 6, 5:30 PM PST)

• Safety and Efficacy of Ruxolitinib in an Open-Label, Multicenter, Single-Arm, Expanded-Access Study in Patients With Myelofibrosis: an 1144-Patient Update (ASH Abstract #3197; December 7, 6:00 PM PST)

Other pipeline studies of note being presented at ASH and SABCS include:

• Phase I Study Update of the Novel Pan-Pim Kinase Inhibitor LGH447 in Patients with Relapsed/Refractory Multiple Myeloma (ASH Abstract #301; December 8, 7:00 AM PST)
• ABL001, a Potent Allosteric Inhibitor of BCR-ABL, Prevents Emergence of Resistant Disease When Administered in Combination with Nilotinib in an in Vivo Murine Model of Chronic Myeloid Leukemia (ASH Abstract #398; December 8, 10:45 AM PST)

• An Open-Label Phase II Study of Buparlisib (BKM120) in Patients with Relapsed and Refractory Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma or Follicular Lymphoma (ASH Abstract #1718; December 6, 5:30 PM PST)

• Midostaurin (PKC412) in Patients with Advanced Systemic Mastocytosis: Results from the Fully Accrued Global Phase II CPKC412D2201 Trial (ASH Abstract #636; December 8, 5:45 PM PST)

• The Signature Program, a Distinctive Tissue Agnostic Trial Model for Molecularly Pre-Selected Hematological and Solid Tumor Patients (ASH Abstract #4818; December 8, 6:00 PM PST)

• A Phase I study of BKM120 and fulvestrant in postmenopausal women with estrogen receptor positive metastatic breast cancer (SABCS Abstract # PD5-6; December 12, 5:00 PM CDT)

• Phase I trial: PI3Kα inhibitor BYL719 plus aromatase inhibitor (AI) for patients with hormone receptor-positive (HR+) metastatic breast cancer (MBC)(SABCS Abstract # PD5-3; December 12, 5:00 PM CDT)

• Phase I study of the PI3Kα inhibitor BYL719 plus fulvestrant in patients with PIK3CA altered and wild type ER+/HER2– locally advanced or metastatic breast cancer (SABCS Abstract # PD5-5; December 12, 5:00 PM CDT)

• Phase Ib/II study of LEE011 and BYL719 and letrozole in ER+, HER2– breast cancer: safety, preliminary efficacy and molecular analysis (SABCS Abstract # P5-19-24; December 12, 5:00 PM CDT)

Throughout ASH and SABCS 2014, Novartis Oncology will host dedicated webpages (http://www.novartisoncology.com/ASH-2014.jsp and http://www.novartisoncology.com/SABCS-2014.jsp) that will provide 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.


Because CTL019, BKM120, LGH447, BYL719, LDE225, PKC412, LBH589, ABL001 and LEE011 are investigational compounds or combinations that are under investigation, 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 CTL019, BKM120, LGH447, BYL719, LDE225, PKC412, LBH589, ABL001 and LEE011 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 “will,” “we’ll,” “look forward,” “investigational,” “focus,” “exploring,” “yet,” “potential,” or similar terms, or by express or implied discussions regarding potential marketing approvals for CTL019, BKM120, LGH447, BYL719, LDE225, PKC412, LBH589, ABL001 and LEE011, potential new indications or labeling for Jakavi, Afinitor,
Tasigna, Glivec and Exjade, or regarding potential future revenues from such investigational compounds and marketed products. 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 CTL019, BKM120, LGH447, BYL719, LDE225, PKC412, LBH589, ABL001 or LEE011 will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that any of Jakavi, Afinitor, Tasigna, Glivec or Exjade 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 investigational compounds and marketed products will be commercially successful in the future. In particular, management’s expectations regarding such investigational compounds and marketed products 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 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, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 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 133,000 full-time-equivalent associates and sell products in more than 150 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.

References

1. American Society of Hematology. ASH Annual 2014 Meeting Program. Available at: https://ash.confex.com/ash/2014/webprogram/meeting.html

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