Novartis presents key advances in cancer research at ASCO and EHA from four new pivotal studies in lung, blood and skin cancers

- Pivotal data in ALK+ NSCLC for Zykadia™; recently approved by US FDA, marking fastest oncology approval under Breakthrough Therapy designation
- First presentation of pivotal data from Phase III trial of Jakavi® in polycythemia vera and LBH589 in multiple myeloma; blood cancers with unmet medical need
- New LDE225 pivotal data unveiled in patients with advanced basal cell carcinoma, the most common form of skin cancer with limited treatment options
- More than 150 abstracts highlighting Novartis therapies include latest analyses of Tasigna®, Afinitor® and Exjade®, as well as pipeline combinations

Basel, May 22, 2014 – Novartis will showcase the results of research efforts to target disease pathways with more than 150 abstracts at two upcoming cancer-focused meetings, including updated data in ALK+ non-small cell lung cancer and the first-ever presentations of key data in polycythemia vera, multiple myeloma (blood) and locally advanced or metastatic basal cell carcinoma (skin).

Clinical data featured at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO; May 30-June 3, Chicago) and the 19th Congress of the European Hematology Association (EHA; June 12-15, Milan) will include Zykadia™ (ceritinib), Jakavi® (ruxolitinib), Tasigna® (nilotinib), Afinitor® (everolimus) and Exjade® (deferasirox), as well as pipeline compounds LBH589 (panobinostat), LDE225 (sonidegib) and others1,2.

“Our research strategy continues to focus on the underlying cause of disease to develop targeted compounds or combinations of therapies,” said Alessandro Riva, MD, President, Novartis Oncology ad interim and Global Head, Oncology Development and Medical Affairs. “The approach has been shown to be successful in treating patients with lung, blood and breast cancers, and this latest research shows that we may have potential new treatments to continue addressing critical needs in cancer care.”

Data highlights include:

Key pivotal data across four oncology compounds
- Ceritinib: Ceritinib in advanced anaplastic lymphoma kinase (ALK)-rearranged (ALK+) non-small cell lung cancer (NSCLC): Results of the ASCEND-1 trial (ASCO oral presentation, abstract #8003; June 2, 3:48 PM CDT)
- Ruxolitinib: Results of a prospective, randomized, open-label Phase III study of ruxolitinib in polycythemia vera patients resistant to or intolerant of hydroxyurea:

1Jakavi 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.
the RESPONSE trial (ASCO oral presentation, abstract #7026; June 3, 9:57 AM CDT; EHA oral presentation, abstract #LB-2436; June 14, 2:00 PM CEST)

- **Panobinostat**: PANORAMA 1: A randomized, double-blind, Phase III study of panobinostat or placebo plus bortezomib and dexamethasone in relapsed or relapsed and refractory multiple myeloma (ASCO oral presentation, abstract #8510; June 2, 8:00 AM CDT; EHA oral presentation, abstract #S641; June 14, 8:00 AM CEST)

- **Sonidegib**: Randomized, double-blind study of sonidegib (LDE225) in patients with locally advanced or metastatic basal cell carcinoma (ASCO oral presentation, abstract #9009a; June 1, 8:00 AM CDT)

**Emerging data on key Novartis marketed treatments, early combination studies and innovative clinical trial designs**

- **Everolimus**: Meta-analysis of stomatitis incidence in everolimus clinical studies and its relationship with efficacy (ASCO abstract #645; June 2, 8:00 AM CDT)

- **Everolimus**: Prevention of stomatitis in patients with hormone receptor-positive advanced breast cancer treated with everolimus plus exemestane: A Phase II study of a steroid-based mouthwash (ASCO trials in progress abstract #TPS661; June 2, 8:00 AM CDT)

- **Everolimus**: Identification and validation of predictive biomarkers for everolimus in metastatic renal cell carcinoma: Analysis of 442 patients on RECORD-3 (ASCO abstract #4631; May 30, 1:00 PM CDT)

- **Nilotinib**: Treatment-free remission following nilotinib in patients with chronic myeloid leukemia in chronic phase: ENESTfreedom, ENESTop, ENESTgoal, and ENESTpath (ASCO trials in progress abstract #TPS7124; June 2, 1:15 PM CDT)

- **Nilotinib**: ENESTnd 5-year update: Long-term outcomes of patients with chronic myeloid leukemia in chronic phase treated with frontline nilotinib vs imatinib (ASCO abstract #7073; June 2, 1:15 PM CDT; EHA oral presentation, abstract #S677; June 14, 8:15 AM CEST)

- **Nilotinib**: Effect of continued imatinib in patients with detectable BCR-ABL after ≥ 2 years on study on deep molecular responses (MR): 36-month update from ENESTcmr (ASCO abstract #7025; May 31, 1:15 PM CDT; EHA oral presentation, abstract #S1361; June 15, 10:45 AM CEST)

- **Ruxolitinib**: Phase Ib, dose-finding study of ruxolitinib plus panobinostat in patients with myelofibrosis (ASCO abstract #7022; May 31, 1:15 PM CDT; EHA abstract #P410; June 13, 5:45-7:00 CEST)

- **Deferasirox**: Deferasirox– deferoxamine combination therapy reduces cardiac iron with rapid liver iron removal after 24 months in patients with severe transfusional iron overload (HYPERION) (EHA abstract #S661; June 14, 8:00 AM CEST)

- The signature program, a series of tissue-agnostic, mutation-specific signal finding trials (ASCO trials in progress abstract #TPS2646; June 1, 8:00 AM CDT)

**New findings from combination studies across oncology pipeline and presentations on CAR T cell therapy**

- **INC280**: Safety and efficacy of INC280 in combination with gefitinib in patients with EGFR-mutated, MET-positive NSCLC: A single-arm Phase Ib/II study (ASCO abstract #8017; June 3, 8:00 AM CDT)

- **LEE011**: Phase Ib/II study of LEE011, everolimus, and exemestane in postmenopausal women with ER+/HER2- metastatic breast cancer (ASCO abstract #535; June 1, 8:00 AM CDT)

- **LEE011**: Phase Ib study of LEE011 and BYL719 in combination with letrozole in estrogen receptor-positive, HER2-negative breast cancer (ASCO abstract #533; June 1, 8:00 AM CDT)

- **CTL019**: Genetically Engineered T Cells and Beyond: Immune Modulation Therapy in Chronic Lymphocytic Leukemia (ASCO; June 2, 1:55 PM CDT)

- **CTL019**: Future Directions in Immune Targeting (ASCO; June 2, 1:35 PM CDT)
Throughout ASCO and EHA, Novartis Oncology will host a dedicated webpage (http://www.novartisoncology.com/asco-2014.jsp) that will provide unique insights and perspectives into 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 LBH589, LDE225, INC280, LEE011, BYL719 and CTL019 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 LBH589, LDE225, INC280, LEE011, BYL719 and/or CTL019 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 “presents,” “will,” “upcoming,” “pipeline,” “strategy,” “continues,” “to focus,” “to develop,” “may,” “potential,” “to continue,” “emerging,” “in progress,” “investigational,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Zykadia, Jakavi, Tasigna, Glivec, Afinitor or Exjade, potential marketing approvals for LBH589, LDE225, INC280, LEE011, BYL719, CTL019 or other investigational treatments in the Novartis Oncology pipeline or regarding potential future revenues from such 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 LBH589, LDE225, INC280, LEE011, BYL719, CTL019 or any other investigational treatment in the Novartis Oncology pipeline will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Zykadia, Jakavi, Tasigna, Glivec, Afinitor 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 products and investigational treatments will be commercially successful in the future. In particular, management’s expectations regarding such products and investigational treatments 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 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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