Novartis data on 19 compounds at AACR highlight strong cancer pipeline across multiple molecular targets and biological pathways

- More than 50 abstracts highlight breadth and depth of Novartis Oncology pipeline and ability to test various combinations early to target multiple pathways

- Data show activity of investigational compounds targeting key pathways, including CDK4/6, PI3K, ALK and FGFR, involved in a variety of cancers

- Several featured compounds have entered Phase III trials including LEE011, a CDK4/6 inhibitor being studied in patients with HR+ breast cancer

Basel, Switzerland, April 3, 2014 – Novartis announced today that early stage data on 19 investigational compounds in its oncology pipeline will be presented at the annual meeting of the American Association of Cancer Research (AACR), April 5-9, 2014 in San Diego, CA. The AACR annual meeting highlights basic, translational and clinical discoveries in oncology. The investigational compounds featured in these Novartis studies are directed at multiple molecular targets and pathways. Currently Novartis Oncology is exploring more than 30 targets involved in cancer.

“Our research approach is driven by an understanding of cancers on a genomic level and developing therapies directed at those targets,” said Alessandro Riva, President, Novartis Oncology ad interim and Global Head, Oncology Development and Medical Affairs. “The AACR presentations demonstrate the depth and breadth of our pipeline, which allows us to test various combinations at an early stage to target different pathways and mutations involved in cancer.”

Among the data being presented are single agent and combination studies with key investigational compounds in the Novartis Oncology breast cancer development program, including an early phase study of the CDK4/6 inhibitor LEE011 and PI3K inhibitors BKM120 and BYL719. LEE011 and BKM120 are currently in Phase III and BYL719 is in Phase I trials for the treatment of advanced breast cancer.

In addition, preclinical data on ALK-inhibitor LDK378 (ceritinib) in ALK-positive non-small cell lung cancer (NSCLC) will be presented at the meeting. LDK378 was granted Breakthrough Therapy Designation by the US Food and Drug Administration (FDA) in 2013 and is currently under review by the FDA.

Early data will be presented on three additional investigational compounds including BGJ398, a highly specific fibroblast growth factor receptor (FGFR) inhibitor that Novartis is exploring in a variety of FGFR-driven solid tumors. A Phase I study of BGJ398 provides the first clinical evidence of activity against cancers that are driven by dysregulation of the FGFR pathway. In addition, the first data on CGM097, a selective p53-Mdm2 inhibitor currently under evaluation in Phase I trials in patients with p53 wild type tumors, and EGF816, a mutant-selective third generation EGFR inhibitor that is entering Phase I trials, will be presented.
More than 50 abstracts involving Novartis investigational compounds will be presented at AACR, including:

**LEE011/BMK120/BYL719**
- *In vivo* efficacy of combined targeting of CDK4/6, ER and PI3K signaling in ER+ breast cancer (Abstract #4756; April 8, 4:05 p.m.)

**BYL719**
- Loss of PTEN leads to clinical resistance to the PI3K inhibitor BYL719 and provides evidence of convergent evolution under selective therapeutic pressure (Abstract #LB327; April 8, 3:50 p.m.; this abstract will also be presented as part of the official AACR press briefing on April 8 at 7:30 a.m.)

**LDK378**
- The ALK inhibitor LDK378 overcomes crizotinib resistance in non-small cell lung cancer (Abstract #957; April 6, 4:05 p.m.)
- Combination CDK4/6 and ALK inhibition demonstrates on-target synergy against neuroblastoma (Abstract #1000; April 6, 4:35 p.m.)
- The Mdm2 inhibitor NVP-CGM097 enhances the anti-tumor activity of NVP-LDK378 in ALK mutant neuroblastoma models (Abstract #2929; April 7, 4:35 p.m.)

**BGJ398**
- Phase I study of BGJ398, a selective pan-FGFR inhibitor in genetically preselected advanced solid tumors (Abstract #CT326; April 8, 10:50 a.m.; this abstract will also be presented as part of the official AACR press briefing on April 8 at 7:30 a.m.)

**CGM097**
- Pre-clinical characterization and clinical development of NVP-CGM097, a highly selective and optimized small-molecule inhibitor of p53-Mdm2 protein-protein interaction (Abstract #ED37-01; April 5, 3:15 p.m.)
- Discovery of NVP-CGM097 as a novel Mdm2 inhibitor (Abstract #DDT01-01; April 6, 1:00 p.m.)
- A gene signature composed of 13 p53 target genes predicts for response to NVP-CGM097, a novel p53-Mdm2 inhibitor, in cell lines and in human primary tumor xenograft models (Abstract #2909; April 7, 3:00 p.m.)
- The Mdm2 inhibitor, NVP-CGM097, in combination with the BRAF inhibitor NVP-LGX818 elicits synergistic antitumor effects in melanoma (Abstract #5466; April 9, 8:00 a.m.)

**EGF816**
- EGF816, a novel covalent inhibitor of mutant-selective epidermal growth factor receptor, overcomes T790M-mediated resistance in NSCLC (Abstract #1733; April 7, 2014, 8:00 a.m.)
- *In vitro* characterization of EGF816, a third-generation mutant-selective EGFR inhibitor (Abstract #1734; April 7, 8:00 a.m.)

**About LEE011, BKM120, BYL719, LDK378, BGJ398, CGM097, LGX818 and EGF816**
Because these are investigational compounds, the safety and efficacy profiles of LEE011, BKM120, BYL719, LDK378, BGJ398, CGM097, LGX818 and EGF816 have not yet been 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 treatments. Because of the uncertainty of clinical trials, there is no guarantee that LEE011, BKM120, BYL719, LDK378, BGJ398, CGM097, LGX818 and EGF816 will ever be commercially available
anywhere in the world. The prefix NVP before a code name is the same compound as the code name alone.

LEE011 was discovered as part of a drug discovery collaboration between the Novartis Institutes for Biomedical Research and Astex Pharmaceuticals.

The BYL719 and BGJ398 abstracts will be presented as part of an official AACR press briefing on Tuesday April 8 at 7:30 a.m. PT in room 15B of the San Diego Convention Center. Reporters unable to attend in person can dial in by calling 1 (866) 297-6395 (US/Canada) or 1 (847) 944-7317 (International), confirmation code: 36855822.

For more information, please visit www.novartisoncology.com.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “pipeline,” “investigational,” “will,” “exploring,” “being presented,” “leads to,” “predicts,” “yet,” “designed,” “potential,” or similar terms, or by express or implied discussions regarding potential marketing authorizations for LEE011, BKM120, BYL719, LDK378, BGJ398, CGM097, LGX818, EGF816 or any other Novartis compounds to be presented at the AACR annual meeting, or regarding potential future revenues from such 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 any of such compounds will be approved for sale in any market where such compounds have been submitted, or will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that such compounds will be commercially successful in the future. In particular, management’s expectations regarding such 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 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 and diagnostic tools, 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 136,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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