Novartis presents new data on 21 medicines and 11 investigational compounds at ASCO and EHA

- **Overall survival data for Tafinlar® and Mekinist® combination to be presented in metastatic BRAF V600E/K mutation-positive cutaneous melanoma**
- **New data for Zykadia® in ALK+ non-small cell lung cancer (NSCLC) and first Phase II data for Tafinlar and Mekinist in BRAF mutant NSCLC**
- **Early data indicate the potential of CAR T therapies in a variety of cancers including lymphoma, multiple myeloma and pancreatic cancer**
- **Latest advances in hematology treatments for CML with Tasigna®, CLL with Arzerra®, multiple myeloma with Farydak®, and polycythemia vera with Jakavi®**

**Basel, May 27, 2015** – Novartis will highlight the strength of its expanded oncology portfolio in 21 medicines and 11 investigational compounds across more than 185 data presentations at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting, May 29-June 2, and the Congress of the European Hematology Association (EHA), June 11-14. Data will demonstrate advances in research in a variety of cancer types, including melanoma, lung, breast, kidney and blood cancers, underscoring Novartis’ leadership in developing treatments with the potential to improve and possibly extend the lives of people with solid and hematologic tumors\(^1,2\).

“Novartis is proud to showcase our portfolio of medicines, enhanced by the acquisition of oncology products and related assets from GSK,” said Bruno Strigini, President of Novartis Oncology. “In addition to new data across many disease areas, we look forward to presenting the overall survival data for the combination regimen of two of the assets we acquired – Tafinlar and Mekinist – as these targeted therapies play a critical role for certain patients fighting metastatic melanoma. These medicines – plus the many others highlighted at ASCO and EHA – exemplify our mission to transform cancer care.”

**Key data presentations show potential benefit of identifying tumor-specific biomarkers and combination treatment strategies:**

- **Tafinlar® (dabrafenib) and Mekinist® (trametinib):** Full COMBI-d overall survival data in metastatic BRAF V600E/K mutation-positive cutaneous melanoma (ASCO Abstract #102; May 31, 9:45 AM CDT), and interim results of a Phase II study of the BRAF inhibitor dabrafenib in combination with the MEK inhibitor trametinib in patients with BRAF V600E mutated metastatic non-small cell lung cancer (ASCO Abstract #8006; May 31, 10:00 AM CDT)
- **Zykadia® (ceritinib):** First presentation of data from Phase II ASCEND-2 and ASCEND-3 efficacy and safety studies in ALK+ non-small cell lung cancer (NSCLC) (ASCO Abstract #8059; June 1, 8:00 AM CDT); (ASCO Abstract #8060; June 1, 8:00 AM CDT)
- **Afinitor® (everolimus):** Identification of efficacy biomarkers in a large metastatic renal cell carcinoma cohort through next-generation sequencing; results from RECORD 3 (ASCO Abstract #4509; June 2, 9:45 AM CDT); biomarker analysis of
“Our significant presence at ASCO demonstrates that Novartis is at the forefront of transforming how cancer is managed and treated, with a commitment to genomic medicine, innovative combinations, as well as the pursuit of scientific partnerships to further advance drug discovery and development,” said Alessandro Riva, MD, Global Head, Novartis Oncology Development and Medical Affairs. “Our broad portfolio illustrates how we use scientific insights to ‘starve or destroy’ cancer cells implicated in a wide range of tumor types.”

Additional data being presented at ASCO and EHA evaluate efficacy and safety of targeting multiple cancer pathways in a variety of solid tumors and blood cancers:

- Phase I study of dabrafenib in pediatric patients (pts) with relapsed or refractory BRAF V600E high- and low-grade gliomas (HGG, LGG), Langerhans cell histiocytosis (LCH), and other solid tumors (OST) (ASCO Abstract #10004; May 30, 4:12 PM CDT)
- A Phase I/II study of the combination of panobinostat (PAN) and carfilzomib (CFZ) in patients (pts) with relapsed or relapsed/refractory multiple myeloma (MM) (ASCO Abstract #8513; June 2, 11:33 AM CDT)
- Panobinostat plus bortezomib and dexamethasone in patients with relapsed or relapsed and refractory multiple myeloma who received prior bortezomib and IMiDs: A predefined subgroup analysis of PANORAMA 1 (ASCO Abstract #8526; May 31, 8:00 AM CDT) (EHA Abstract #S102; June 12, 11:45 CEST)

Important studies feature Novartis precision medicines and scientific insight based on genomic attributes of specific cancer types:

- Phase I study of ceritinib in pediatric patients (Pts) with malignancies harboring a genetic alteration in ALK (ALK+); Safety, pharmacokinetic (PK), and efficacy results (ASCO Abstract #10005; May 30, 4:24 PM CDT)
- First-in-human Phase I study of EGFR816, a third generation mutant-selective EGFR tyrosine kinase inhibitor, in advanced non-small cell lung cancer (NSCLC) harboring T790M (ASCO Abstract #8013; June 1, 8:00 AM CDT)
- Effect of mutations in distinct components of the PI3K/AKT/mTOR pathway on sensitivity to endocrine therapy in estrogen receptor (ER)-positive breast cancer (ASCO Abstract #532; May 30, 8:00 AM CDT)
- Evaluation of possible linkage between everolimus benefit in estrogen receptor (ER)-positive breast cancer and genomic alterations of the PI3K/AKT/mTOR pathway (ASCO Abstract #530; May 30, 8:00 AM CDT)

Early data indicate the potential of Chimeric Antigen Receptor T cell (CAR T) therapies in a variety of cancers including lymphoma, multiple myeloma and pancreatic cancer:

- Phase IIa trial of chimeric antigen receptor modified T cells directed against CD19 (CTL019) in patients with relapsed or refractory CD19+ lymphomas (ASCO Abstract #8516; June 1, 3:24 PM CDT)
- Safety and efficacy of anti-CD19 chimeric antigen receptor (CAR)-modified autologous T cells (CTL019) in advanced multiple myeloma (ASCO Abstract #8517; June 1, 3:36 PM CDT)
- Safety and antitumor activity of chimeric antigen receptor modified T cells in patients with chemotherapy refractory metastatic pancreatic cancer (ASCO Abstract #3007; June 1, 3:27 PM CDT)

Other noteworthy data to be presented at ASCO and EHA:

- Final overall survival analysis for the RECORD-3 study of first-line everolimus followed by sunitinib versus first-line sunitinib followed by everolimus in metastatic RCC (mRCC) (ASCO Abstract #4554; June 1, 1:15 PM CDT)
• RECORD-4: A multicenter Phase II trial of second-line everolimus (EVE) in patients (pts) with metastatic renal cell carcinoma (mRCC) (ASCO Abstract #4518; June 1, 1:15 PM CDT)
• Efficacy and safety of frontline nilotinib in 1089 European patients (pts) with chronic myeloid leukemia in chronic phase (CML-CP): ENEST1st final analysis (EHA Abstract #S486, June 13, 3:45 PM CEST)
• Efficacy and safety of nilotinib vs. imatinib in newly diagnosed chronic myeloid leukemia in chronic phase: 6-year follow-up of ENESTnd (EHA Abstract #P228, June 12, 5:15 PM CEST)
• ENESTcmr 4-Y results: Patients (pts) with CML in chronic phase (CML-CP) and residual disease more likely to achieve deep molecular response following switch to nilotinib (NIL) (EHA Abstract #P229, June 12, 5:15 PM CEST)
• Ofatumumab (O) in combination with fludarabine (F) and cyclophosphamide (C) (OFC) vs. FC in patients with relapsed chronic lymphocytic leukaemia (CLL): Results of the Phase III study COMPLEMENT 2 (EHA Late-Breaker Abstract #LB219, June 12, 5:15 PM CEST)
• Ruxolitinib in polycythaemia vera: Follow-up from the RESPONSE trial (ASCO Abstract #7087; May 31, 8:00 AM CDT); (EHA Abstract #S447; June 13, 11:45 AM CEST)

Throughout ASCO and EHA, Novartis Oncology will host a dedicated webpage (www.novartisoncology.com/asco-2015.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.

For full prescribing information, including approved indications and important safety information about marketed products, please visit http://www.novartisoncology.com/products.jsp.

Because EGF816 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 EGF816 and 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 “investigational,” “to be presented,” “potential,” “will,” “look forward,” “mission,” “commitment,” or similar terms, or by express or implied discussions regarding potential new indications or labeling for Tafinlar, Mekinist, Zykadia, Afinitor, Farydak, Tasigna, Glivec, Arzerra and Jakavi, potential marketing approvals for EGF816 and CTL019, 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 any such products 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 EGF816 or CTL019 will be submitted or 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 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 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 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.

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