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Novartis investigational compound LBH589 significantly extended time without disease progression in Phase III multiple myeloma study

- *Study of LBH589 plus bortezomib and dexamethasone met primary endpoint of extending PFS compared to bortezomib plus dexamethasone and placebo*
- *LBH589 has potential to be the first in its class of anticancer agents available to patients with multiple myeloma*
- *Data will be presented at an upcoming medical congress and discussed with regulatory authorities worldwide*

Basel, December 6, 2013 – Novartis today announced that results of a Phase III trial of the investigational compound LBH589 (panobinostat) in combination with bortezomib and dexamethasone, met the primary endpoint of significantly extending progression-free survival (PFS) in patients with relapsed or relapsed and refractory multiple myeloma when compared to bortezomib plus dexamethasone alone.

Full results from the PANORAMA-1 (PANobinostat ORAl in Multiple MyelomA) trial, continue to be evaluated and will be presented at an upcoming medical congress and discussed with regulatory authorities worldwide.

Multiple myeloma affects approximately 1 to 5 in every 100,000 people worldwide each year. The five year survival-rate for patients with the disease is about 44%[1].

LBH589 showed significant clinical benefit bringing it a step closer to becoming the first in its class of anticancer agents to be available to patients with multiple myeloma. As a pan-deacetylase (pan-DAC) inhibitor, LBH589 works by blocking a key cancer cell enzyme which ultimately leads to cellular stress and death of these cells[2].

“Results from this study show improved outcomes for these multiple myeloma patients who otherwise have few options to treat this incurable disease,” said Alessandro Riva, Global Head, Oncology Development and Medical Affairs, Novartis Oncology. “Given its mechanism of action, LBH589 has the potential to be an important treatment option for multiple myeloma.”

Prior data demonstrated that oral LBH589, when combined with bortezomib and dexamethasone, recaptures responses in heavily pretreated and bortezomib-refractory multiple myeloma patients, thereby providing these patients with a potential new option after failing prior standard treatments[3]. The compound’s possible benefits and risks are also being explored in additional hematologic malignancies through ongoing clinical trials.

Study Design
The PANobinostat ORAl in Multiple MyelomA (PANORAMA) clinical trial program is evaluating LBH589 in patients with relapsed or relapsed and refractory multiple myeloma.

The PANORAMA-1 clinical trial is a Phase III randomized, double blind, placebo controlled, multicenter global registration trial to evaluate LBH589 in combination with bortezomib and dexamethasone against bortezomib and dexamethasone alone in patients with relapsed or relapsed and refractory multiple myeloma. The primary endpoint of the trial was progression-free survival (PFS) and the key secondary endpoint is overall survival (OS). Other secondary endpoints include overall response rate, duration of response and safety.

About LBH589
LBH589 is a potent oral pan-inhibitor of class I, II, and IV histone (and non-histone) deacetylase enzymes (HDACs/DACs). It works by blocking a set of key enzymes which ultimately leads to cellular stress and death of these cells[2].

Because LBH589 is an investigational compound, the safety and efficacy profile has not yet been established. Access to this investigational compound is available only through carefully controlled and monitored clinical trials. These trials are designed to understand better the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that LBH589 will ever be commercially available anywhere in the world.

About Multiple Myeloma
Multiple myeloma is a cancer of plasma cells, a type of white blood cell in the bone marrow that produces antibodies and helps fight infection. When the plasma cells become cancerous and multiply, they are known as myeloma cells. The buildup of myeloma cells causes an abnormal plasma cell level in the blood, overwhelming the production of healthy cells[4].

Multiple myeloma typically occurs in individuals 50 years of age and older, with few cases in individuals younger than 40. Common symptoms include a high level of calcium in the blood, decreased red blood cells, kidney failure, bone damage and pain and fatigue, but may vary from person to person. There are currently no curative therapies available for multiple myeloma[4]. Therefore, there is a high unmet medical need for therapies addressing new relevant molecular targets.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “investigational,” “potential,” “will,” “upcoming,” “continue,” “on-going,” or similar terms, or by express or implied discussions regarding potential marketing approvals for LBH589, or regarding potential future revenues from LBH589. 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 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that LBH589 will receive regulatory approval or be commercially successful in the future. In particular, management’s expectations regarding LBH589 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 133,000 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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