Novartis receives FDA breakthrough therapy designation for BYM338 (bimagrumab) for sporadic inclusion body myositis (sIBM)

- Designation highlights potential of BYM338 to address an unmet medical need in a serious disease
- If approved, BYM338 has the potential to be the first treatment for sIBM patients
- BYM338 is the third Novartis investigational treatment this year to receive a breakthrough therapy designation by the FDA, highlighting Novartis’ leadership in the industry in breakthrough therapy designations

Basel, August 20, 2013 - Novartis announced today that the US Food and Drug Administration (FDA) has granted breakthrough therapy designation to BYM338 for sporadic inclusion body myositis (sIBM).

Breakthrough therapy designation was created by the FDA to expedite the development and review of new drugs for serious or life-threatening conditions. This designation is based on the results of a Phase II proof-of-concept study that showed BYM338 substantially benefited patients with sIBM compared to placebo. The results of this study will be presented at the American Neurological Association meeting on October 14 and is expected to be published in a major medical journal later this year.

sIBM is a rare yet potentially life-threatening muscle-wasting condition. Patients who have the disease can gradually lose the ability to walk, experience falls and injuries, lose hand function, and have swallowing difficulties¹. There are no currently approved, (or established), treatment options for sIBM².

“BYM338 is the third example this year of Novartis’ leadership in bringing breakthrough therapies to patients reinforcing our commitment to innovation addressing significant unmet medical needs and enhancing the lives of patients,” said Timothy Wright, M.D., Global Head of Development, Novartis Pharmaceuticals. “With no effective therapies currently available for sIBM, bimagrumab has the potential to be the first real option for patients with this condition.”

About BYM338 (bimagrumab) and the Novartis commitment to research in muscle therapeutics

BYM338 (bimagrumab) is a novel, fully human monoclonal antibody developed to treat pathological muscle loss and weakness. BYM338 was developed by the Novartis Institutes for Biomedical Research (NIBR), in collaboration with Morphosys, whose HuCAL library was used to identify the antibody. BYM338 binds with high affinity to type II activin receptors, preventing natural ligands from binding, including myostatin and activin. BYM338 stimulates muscle growth by blocking signaling from these inhibitory molecules.
In addition to being developed for sIBM, BYM338 is in clinical development for chronic obstructive pulmonary disease (COPD), cancer cachexia, sarcopenia and in mechanically ventilated patients. BYM338 is administered by intravenous infusion.

**Breakthrough therapy designation**
According to the FDA, breakthrough therapy designation is intended to expedite the development and review of drugs that treat serious or life-threatening conditions. The designation requires preliminary clinical evidence that demonstrates substantial improvement over currently available therapy. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

**About sporadic inclusion body myositis (sIBM)**
sIBM is a rare disease, yet it is the most common degenerative disease of muscle in adults older than 65 years. It is characterized by a slowly progressive, asymmetric, atrophy and weakness of muscles. Commonly, patients become wheelchair bound within 10 to 15 years of onset. Death may occur due to injurious falls, infection (aspiration pneumonia), or malnutrition.

Bimagrumab also was granted orphan drug designation in sIBM in both the US and Europe in 2012.

**Disclaimer**
The foregoing release contains forward-looking statements that can be identified by terminology "breakthrough therapy", "potential", "will", "expected", "potentially" and "commitment" or similar expressions, or by express or implied discussions regarding potential approvals for BYM338 or regarding potential future revenues from BYM338. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that BYM338 will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that BYM348 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding BYM338 could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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 131,000 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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