Novartis announces AMG 334 significantly reduces patients’ monthly migraine days in phase II study of chronic migraine prevention

- Phase II 20120295 study of AMG 334 met primary endpoint, confirming efficacy and safety in patients with chronic migraine over 12 weeks of treatment

- Migraine is a leading cause of disability, affecting more than 10% of people worldwide – within the overall migraine population, people with chronic migraine experience the greatest impact on daily activities and quality of life

- AMG 334 is being co-developed by Novartis and Amgen

Basel, 8 June 2016 – Novartis today announced positive first results from the global phase II 20120295 study, investigating the efficacy and safety of the fully human monoclonal antibody AMG 334 (erenumab) in chronic migraine prevention. The study evaluated AMG 334 at two doses, 70mg and 140mg, administered subcutaneously once a month, with both doses meeting the study’s primary endpoint of a statistically significant reduction in the number of monthly migraine days versus placebo.

“Patients with chronic migraine live with the debilitating and disabling symptoms of this disease for 15 or more days each month, significantly impacting their everyday life and ability to work,” said Vasant Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “We are delighted that with this positive outcome, we are one step closer to providing patients with a much-needed new treatment option to prevent chronic migraine. Also, we are looking forward to assessing the benefit of AMG 334 in two ongoing phase III studies in episodic migraine, with initial data from these studies expected later this year.”

Overall, patients had a mean baseline of 18 migraine days per month. Patients randomized to the 70mg and 140mg dose groups experienced a mean 6.6-day reduction from baseline in monthly migraine days in both groups. The results were statistically significant compared with 4.2 days observed in the placebo group.

The safety and tolerability profile of AMG 334 was similar to placebo in both treatment groups. No adverse event was reported in greater than five percent of patients treated with AMG 334; the most commonly reported adverse events included injection site pain, infection of the upper respiratory tract and nausea.

Additional analyses of these data are ongoing and are expected to be submitted to a future medical meeting and for publication.

More complex than a headache, migraine is the most prevalent of all neurological disorders, affecting more than 10% of the worldwide population. Migraine has a profound and limiting impact on patients’ abilities to carry out everyday tasks and as a result it is classed as the sixth leading cause of years lived with disability. Chronic migraine patients experience the greatest impact on daily activities and quality of life, with at least 15 headache days per month, of which eight or more are migraines, for more than three months.
AMG 334 is being co-developed by Amgen and Novartis. As part of the collaboration, Amgen retained commercialization rights in the U.S., Canada and Japan, and Novartis has rights in Europe and rest of world.

About the 20120295 Study
The 20120295 study is a global phase II, randomized, 12-week, double-blind, placebo-controlled study evaluating the efficacy and safety of AMG 334 in chronic migraine prevention. In the study, 667 patients were randomized to receive once-monthly subcutaneous placebo or AMG 334 (70mg or 140mg) in a 3:2:2 ratio respectively. The primary outcome measure was the change in monthly migraine days from baseline to the last four weeks of the 12-week treatment phase in patients with chronic migraine (the number of migraine days between weeks 9 and 12). Secondary study endpoints included proportion of patients with at least a 50% reduction from baseline in monthly migraine days in the last four weeks of the 12-week treatment phase (50% responder rate), acute migraine-specific medication use days, cumulative hours of headache, and safety and tolerability.

About Migraine
Migraine involves recurrent attacks of moderate to severe head pain that is typically pulsating, often unilateral and associated with nausea, vomiting and sensitivity to light, sound and odors. Migraine is associated with personal and societal burdens of pain, disability, reduced quality of life and financial cost, and it remains under-recognized and under-treated with more than 40% of people going undiagnosed. Chronic migraine is characterized by at least 15 headache days per month, of which eight or more are migraines, for more than three months.

About AMG 334
AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine. AMG 334 inhibits the activity of Calcitonin-Gene-Related-Peptide (CGRP) by targeting its receptor, which is believed to transmit signals that can cause pain. AMG 334 is currently under evaluation in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in chronic and episodic migraine prevention.

About the Amgen and Novartis Neuroscience Collaboration
In August 2015, Novartis entered into a global collaboration with Amgen to commercialize and develop pioneering neuroscience treatments in the field of Alzheimer’s Disease (AD) and migraine. The companies are partnering in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD. Novartis' oral therapy CNP520 (currently in a phase I/IIa study for AD) will be the lead molecule and further compounds from both companies' pre-clinical BACE inhibitor programs may be considered as follow-on molecules. The collaboration also focuses on investigational Amgen drugs in the migraine field, including AMG 334 (currently in phase III studies for episodic migraine and a phase II study for chronic migraine) and AMG 301 (currently in a phase I study for migraine). For the migraine program, Novartis will have global co-development rights and commercial rights outside the U.S., Canada, and Japan.

About Novartis in Neuroscience
Novartis has a strong ongoing commitment to neuroscience (NS) and to bringing innovative treatments to patients suffering from neurological conditions where there is a high unmet need. We currently offer patients and physicians a large drug portfolio encompassing Multiple Sclerosis (MS), Alzheimer’s disease, Parkinson’s disease, Epilepsy and Attention Deficit Hyperactivity Disorder, and have a promising pipeline in MS, Alzheimer’s disease, migraine and specialty neurology (e.g. neuropathic pain).
Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “one step closer,” “looking forward,” “ongoing,” “expected,” “under investigation,” “under evaluation,” “pioneering,” “will,” “may,” “commitment,” “promising,” “pipeline,” or similar terms, or by express or implied discussions regarding potential marketing approvals for AMG 334, AMG 301, CNP520, and the other investigational compounds of Novartis and Amgen subject to the collaboration, regarding potential new indications or labeling for the products in the Novartis Neuroscience portfolio, or regarding potential future revenues from such products and investigational compounds, and potential future revenues from the collaboration with Amgen. 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 AMG 334, AMG 301, CNP520, and the other investigational compounds of Novartis and Amgen subject to the collaboration will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that any of the products in the Novartis Neuroscience portfolio 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 the collaboration with Amgen will achieve any or all of its intended goals and objectives, or be commercially successful. Neither can there be any guarantee that any of AMG 334, AMG 301, CNP520, the other investigational compounds subject to the collaboration with Amgen, or the products in the Novartis Neuroscience portfolio will be commercially successful in the future. In particular, management’s expectations regarding such investigational compounds and products and the collaboration with Amgen 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 safety, quality or 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 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 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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