FDA Accepts Biologics License Application for AMG 334 (Erenumab), an Important Regulatory Milestone for Novartis

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- AMG 334 (erenumab) is an investigational therapy with a novel mechanism of action for migraine prevention for patients with high unmet need
- Migraine is associated with pain, disability and nearly $25 billion in annual US healthcare costs and is compounded by stigma and misunderstanding(1,2)
- AMG 334 (erenumab) is supported by a large clinical program in more than 2,600 patients, where the number of monthly migraine days was reduced with treatment

EAST HANOVER, N.J., July 20, 2017 /PRNewswire/ -- Novartis today announced that the US Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for AMG 334 (erenumab) for the prevention of migraine in patients experiencing four or more migraine days per month. If approved, erenumab is expected to be the first and only fully human monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) receptor, specifically designed for the prevention of migraine.

"Migraine is a serious, chronic neurological disease with a profound and limiting impact on patients' abilities to carry out everyday tasks," said Vas Narasimhan, Global Head Drug Development and Chief Medical Officer for Novartis. "We look forward to continuing our longstanding history of redefining clinical practice in neurology by working with the FDA to bring erenumab to people suffering from migraine, and to subsequently reduce the overall burden of this debilitating disease."

Phase II and Phase III clinical studies of erenumab versus placebo have demonstrated a significant reduction in the number of migraine-affected days, acute medication over-use and disability, while improving quality of life for patients with episodic and chronic migraine. The safety profile of erenumab was similar to placebo in over 2,600 patients in the Phase II and Phase III studies assessing the prevention of migraine, and persistence rates were approximately 90 percent.

Erenumab will be jointly commercialized in the US by Amgen and Novartis.

About AMG 334 (Erenumab)
AMG 334 (erenumab) is the only fully human monoclonal antibody specifically designed for the prevention of migraine that has been filed with the FDA. Erenumab specifically inhibits the receptor of the calcitonin gene-related peptide (CGRP), which is thought to play a causal role in migraine pathophysiology. Erenumab has been studied in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention.

About Migraine
Migraine is a distinct neurological disease.[3] People with migraine lose a substantial portion of their lives to this illness, experiencing significant physical impairment, frequently accompanied by head pain, nausea, vomiting and meaningful disruption of daily activities.[3] The World Health Organization ranks migraine as one of the

most debilitating illnesses.[4] For the approximately 10 million Americans whose migraine frequency or severity impacts daily activities, preventive medications may be an option.[5] Approximately 3.5 million of these patients are currently on a preventive therapy, but up to 80 percent are non-adherent within one year.[5,6] Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized, under-treated, and compounded by stigma and misunderstanding.

About Novartis and Amgen Neuroscience Collaboration

In August 2015, Novartis entered into a global collaboration with Amgen to jointly develop and commercialize pioneering neuroscience treatments in the field of migraine and Alzheimer's disease (AD). The collaboration focuses on investigational drugs in the migraine field, including erenumab (Biologics License Application accepted by the US FDA in July 2017) and AMG 301 (currently in Phase I development). In April 2017, the collaboration was expanded to include co-commercialization of erenumab in the US. For the migraine program, Amgen retains exclusive rights in Japan, and Novartis has exclusive rights in Europe, Canada and rest of world. Also, the companies are collaborating in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD. The oral therapy CNP520 (currently in Phase III for AD) is the lead molecule and further compounds from both companies' pre-clinical BACE inhibitor programs may be considered as follow-on molecules.

Novartis in Neuroscience

Novartis has a strong ongoing commitment to neuroscience and to bringing innovative treatments to patients suffering from neurological conditions where there is a high unmet need. We are committed to supporting patients and physicians in multiple disease areas, including 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

This press release contains forward-looking statements, including "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "milestone," "investigational," "expected," "look forward," "continuing," "would," "step toward," "potential," "ongoing," "commitment," "may," "pioneering," "committed," "promising," "pipeline," "will," "submitted," or similar terms, or by express or implied discussions regarding potential marketing approvals for AMG 334, CNP520, AMG 301, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the collaboration, potential new indications or labeling for products in the Novartis Neuroscience portfolio, or regarding potential future revenues from such investigational compounds and products, 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 our current beliefs and expectations 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, CNP520, AMG 301, other BACE inhibitors of Novartis and Amgen, or 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 the collaboration with Amgen will achieve any or all of its intended goals and objectives, or be commercially successful. Nor can there be any guarantee that any product in the Novartis Neuroscience portfolio 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 AMG 334, CNP520, AMG 301, any of the other investigational compounds subject to the collaboration with Amgen, or any product in the Novartis Neuroscience portfolio will be commercially successful in the future. In particular, our 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 clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; 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
Located in East Hanover, NJ Novartis Pharmaceuticals Corporation is an affiliate of Novartis which 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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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