Novartis and Amgen announce FDA approval of Aimovig™ (erenumab-aooe), a novel treatment developed specifically for migraine prevention

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- - Migraine is a severe neurologic disease that profoundly impacts millions of patients in the United States
- - Aimovig is the first and only FDA-approved treatment to block the calcitonin gene-related peptide receptor (CGRP-R), which plays an important role in migraine
- - Aimovig was consistently shown to reduce monthly migraine days, including in more difficult-to-treat populations, with many patients achieving at least a 50% reduction

EAST HANOVER, N.J., May 17, 2018 /PRNewswire/ -- Novartis today announced that the US Food and Drug Administration (FDA) has approved Aimovig™ (erenumab-aooe) for the preventive treatment of migraine in adults. Aimovig is a novel therapeutic approach as the first and only FDA-approved treatment specifically developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R), which is believed to play a critical role in migraine. Aimovig 70 mg is self-administered once monthly via Amgen's device, the SureClick® autoinjector, and does not require a loading dose. Some patients may benefit from a dosage of 140 mg once monthly.

"The FDA approval of Aimovig reflects the Novartis commitment to advancing neuroscience and marks an important moment in the fight against migraine," said Fabrice Chouraqui, US President of Novartis Pharmaceuticals Corporation. "Migraine is a serious and misunderstood disease with significant gaps in the way it is both perceived and treated. In close partnership with Amgen, our goal in the US is to bring meaningful therapeutic options to patients, while also helping them to overcome the personal, professional and clinical barriers that have long been associated with this stigmatized disease."

In Phase II and III studies in chronic and episodic migraine, Aimovig resulted in significant reductions in monthly migraine days and use of acute migraine medications compared to placebo. These effects on monthly migraine days have been shown to be sustained for up to 15 months in an ongoing open-label extension study in episodic migraine (four to 14 headache days per month).

A dedicated Phase IIIb study (LIBERTY) in difficult-to-treat populations – those with episodic migraine who have failed two to four prior treatments – showed that patients taking Aimovig had nearly three-fold higher odds of having their migraine days cut by half or more compared to placebo.

The efficacy, tolerability and safety of Aimovig has been assessed in more than 3,000 patients, including LIBERTY and an ongoing open-label extension of up to five years in duration. In clinical studies of Aimovig, the most common adverse reactions were injection site reactions and constipation.

"Having a treatment designed to specifically address the complex nature of migraine is an important and welcome step forward in headache medicine. Aimovig offers self-administration with proven efficacy across a spectrum of patients, including in those who have previously tried other preventive therapies without success," said Stewart J. Tepper, MD, Professor of Neurology at the Geisel School of Medicine at Dartmouth Medical School. "Importantly, in clinical trials, Aimovig patients were able to start and stay on therapy – with a

discontinuation rate of two percent due to adverse events – and experienced sustained migraine prevention."

"For years, the migraine community has been advocating for new treatment options that are specifically designed to treat migraine, a debilitating and often stigmatized disease," said Kevin Lenaburg, Executive Director of the Coalition For Headache And Migraine Patients (CHAMP), which represents 12 national headache and migraine patient advocacy groups. "Today we celebrate the tireless work of researchers to better understand the biology of migraine and their ability to bring a new therapeutic approach to the millions of Americans who are seeking fewer migraine days. On behalf of the community, we would also like to thank the thousands of clinical trial patients whose unwavering commitment made this progress possible."

Amgen and Novartis are committed to supporting the migraine community and to helping appropriate patients with affordable access to Aimovig. The Aimovig Ally™ product support program has been created to help patients navigate insurance coverage and identify potential access resources for those who are uninsured or underinsured.

The US list price of Aimovig is $575 for once monthly 70 or 140 mg single-use prefilled SureClick® autoinjectors, or $6,900 annually. The price of Aimovig reflects the value it brings to patients and society, including the financial impact on sufferers, caregivers and employers, while also factoring in critical issues such as patient affordability, and fair and timely access.

While out-of-pocket costs will vary depending on insurance status, the Aimovig Copay Program may be able to help reduce a patient's out-of-pocket costs to as little as $5 per month for eligible patients with commercial insurance. For more information about Aimovig Ally™ and the Aimovig Copay Program, please visit www.aimovig.com.

Aimovig is expected to be available to patients within one week.

The European Medicines Agency (EMA) Marketing Authorization Application (MAA) for Aimovig is under review. Novartis expects approval in the EU in the coming months.

About Aimovig™ (erenumab-aooe)
Aimovig is the only FDA-approved treatment specifically developed to prevent migraine by blocking the CGRP-R, which is associated with migraine. Aimovig has been studied in several large global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention. More than 3,000 patients have participated in the Aimovig clinical program across four placebo-controlled Phase II and Phase III clinical studies and their open-label extensions.

About LIBERTY
LIBERTY (NCT03096834) is a Phase IIIb, multicenter, randomized 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of Aimovig in patients with episodic migraine (defined in the trial as four to 14 migraine days per month at baseline) who have failed up to four prior preventive treatments for migraine. In the study, 246 participants with episodic migraine who had two to four previous treatment failures were randomized to receive Aimovig 140 mg or placebo during the 12-week double-blind treatment phase. The primary endpoint was the percentage of patients with at least a 50 percent reduction of monthly migraine days from baseline over the last four weeks of the double-blind treatment phase of the study (weeks 9-12).[1]

US Aimovig Indication

Aimovig is indicated for the preventive treatment of migraine in adults.

US Aimovig Important Safety Information

- The most common adverse reactions in clinical studies (≥ 3% of Aimovig™-treated patients and more often than placebo) were injection site reactions and constipation.

Please visit www.pharma.us.novartis.com or www.aimovig.com for Full US Prescribing Information.

About Migraine
People with frequent migraine may lose more than half their life to migraine. They endure debilitating pain, physical impairment, and live in constant dread of the next attack – all of which is compounded by a widespread misperception of the disease.[2] The 2016 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide.[3] Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated.[2]

About Novartis and Amgen Neuroscience Collaboration
In August 2015, Novartis entered into a global collaboration with Amgen to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease. The collaboration focuses on investigational Amgen drugs in the migraine field, including Aimovig (approved by the FDA in May 2018 for the preventive treatment of migraine in adults) and AMG 301 (currently in Phase II development). In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the US. For the migraine program, Amgen retains exclusive commercialization rights in Japan, and Novartis has exclusive commercialization 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 Alzheimer's disease. The oral therapy CNP520 (currently in Phase III for Alzheimer's disease) is the lead molecule and further compounds from both companies' pre-clinical BACE inhibitor programs may be considered as follow-on molecules. At the center of the Amgen and Novartis neuroscience collaboration is the shared mission to fight migraine and the stereotypes and misperceptions surrounding this debilitating disease.

About the Novartis and Amgen Migraine Mission
Migraine has gone under-appreciated and under-treated for too long. In addition to bringing Aimovig to market, Amgen and Novartis have committed to leading the charge together against migraine misperceptions. Through outreach and education our goal is to challenge public perception of migraine disease, assist people in getting the treatment they need and facilitate informed communication among people with migraine and those who live and work with them, including co-workers, employers and insurers. Future initiatives will include a focus on addressing how stigma against migraine manifests in the workplace: migraine gets in between people and their careers, and in between employee and employer. We hope our workplace program will serve as an example to coworkers, employers and human resources to help each party understand why and how they should treat migraine as a serious disease.

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 within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "expected," "expects," "believed," "ongoing," "commitment," "committed," "step forward," "investigational," "promising," "pipeline," "will," "may," "goal," "mission," "hope," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Aimovig or the

other investigational or approved products described in this press release, or regarding potential future revenues from such products or 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 Aimovig or the other investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling 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 Aimovig or the other investigational or approved products described in this press release will be commercially successful in the future. In particular, our expectations regarding such 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; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 124,000 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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