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Novartis announces data in *Neurology* reinforcing the real-world and long-term effectiveness and safety of Aimovig® as a preventive treatment across the full spectrum of migraine

- *Real-world evidence supports benefits seen in Aimovig clinical trials*
- *Open-label data highlight long-term efficacy and safety profile of Aimovig in episodic and chronic migraine*
- *Post-hoc and real-world data show preventive treatment with Aimovig significantly reduces need for acute medications*
- *These additional long-term data complement the position of Aimovig as the most prescribed anti-CGRP, with more than 350,000 patients prescribed worldwide since launch*[1]

Basel, April 16, 2020 — Novartis today announced that clinical data for Aimovig® (erenumab) was reported in *Neurology*. The data strengthens the role Aimovig as a preventive migraine treatment and confirms its real-world and long-term safety and efficacy benefit in patients with episodic and chronic migraine. The data were scheduled to be presented at the 2020 American Academy of Neurology Annual Meeting in Toronto on April 25-May 1, which was cancelled due to the current COVID-19 pandemic.

“These newly shared data reinforce Novartis commitment to reimagine migraine care and add to the growing body of real world and long-term evidence demonstrating the efficacy of Aimovig for migraine prevention across the migraine spectrum,” said Estelle Vester-Blokland, Global Head Neuroscience Medical Affairs, Novartis Pharmaceuticals. “Novartis and Amgen are proud to lead the way based on the vast breadth of experience with Aimovig in showing how patients can take their life back from this highly debilitating disease.”

Migraine is a highly debilitating disease that has a profound and limiting impact on peoples' lives, including time spent with family and friends, or at work[2,3]. Aimovig, co-marketed in the US by Amgen and Novartis, is the first and only FDA-approved migraine preventive treatment that targets the calcitonin gene-related peptide (CGRP) receptor. It is self-administered once monthly via the SureClick® autoinjector, does not require a loading dose and is easy to use[4].

Real-world Data
Interim exploratory results from the real-world TELESCOPE study, conducted with 109 patients in Germany, showed that 80% of patients taking Aimovig reported a reduction of

migraine intensity and 92% had fewer attacks, with an average reduction of 8 monthly migraine days (MMD). Furthermore, interim results from the real-world PERISCOPE study in 19,740 migraine patients including 91 patients taking Aimovig with an overall mean disease duration of 18 years, also conducted in Germany, showed that 85% of patients taking Aimovig could cope better with daily activities. Importantly, 83% lost fewer days to migraine since starting the treatment.

Long-term Data in Episodic and Chronic Migraine
Results from a 4.5-year interim analysis of the open-label treatment phase of the Phase II clinical trial in patients with episodic migraine showed that long-term treatment with Aimovig resulted in sustained reductions in MMD. Patients with episodic migraine who switched from 70 mg to 140 mg and remained on 140 mg at ≥4 years, had an average of 5.8 fewer MMD compared with study baseline (8.7 MMD).

In a separate subanalysis of patients with chronic migraine and acute medication overuse (AMO) (NCT02066415), long-term treatment with 70 mg and 140 mg Aimovig reduced MMD by 8.9 days and 10 days, respectively, and by 8.2 and 10.8 days in non-AMO patients. These results further support the use of Aimovig for migraine prevention across the migraine spectrum. Final results are expected to be presented at a medical meeting later this year.

Data on Migraine Days and Acute Medication Use
Results from a post-hoc analysis of 428 patients with episodic (STRIVE, NCT02456740) and 457 patients with chronic migraine (NCT02066415) using acute migraine specific medications (AMSM) showed that preventive treatment with Aimovig plus AMSM as needed significantly reduced MMD, AMSM use and disability compared with AMSMs alone.

Further research using real-word data from pharmacy and medical claims databases reinforced the potential benefits of Aimovig over AMSMs. In this retrospective cohort study using data from 43 of 185 patients, more than one-third of those who initiated Aimovig discontinued AMSMs and more than 80% reduced the amount (units) of AMSM used.

About Aimovig (erenumab)
Aimovig is the first EMA, Swissmedic, Australian TGA and FDA-approved migraine prevention treatment designed specifically to block the CGRP-R, which plays a critical role in 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 our overall clinical trial program. This includes 2,600 participants across the four placebo-controlled pivotal Phase II and Phase III clinical studies as well as participants in further studies such as LIBERTY, a dedicated study in a difficult-to-treat treatment failure population. The most common side effects in the clinical program to date have been viral upper respiratory tract infection, sinusitis, influenza, and back pain.

Novartis and Amgen are co-commercializing Aimovig in the US. Amgen has exclusive commercialization rights to the drug in Japan and Novartis has exclusive rights to commercialize in the rest of the world.

About Migraine
Migraine is a distinct neurological disease[5]. It 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[6]. Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society[7]. It has a profound and limiting impact on an individual's abilities to carry out everyday tasks; the World Health Organization reported migraine to be one of the top 10 causes of years lived with disability for men and women[8]. It remains under-recognized and under-treated[7,9].

About the Amgen and Novartis Neuroscience Collaboration
In August 2015, Amgen entered into a global collaboration with Novartis to develop and commercialize pioneering treatments in the field of migraine. 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). In April 2017, Novartis obtained co-commercialization rights of Aimovig in the US. For the migraine programs, Amgen retains exclusive commercialization rights in the US (other than for Aimovig as described above) and Japan. Novartis has exclusive commercialization rights in Europe, Canada and rest of the world. 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.

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,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. 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 the 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. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products 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 and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity 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

Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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