Novartis announces five-year data that reinforce the safety and efficacy profile of Aimovig® (erenumab-aooe) in adult patients with episodic migraine

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- Results presented at the Migraine Trust Virtual Symposium highlight long-term benefit of Aimovig
- Aimovig has the longest duration of safety and efficacy trial data for any anti-CGRP pathway therapy
- Five-year open-label extension study shows patients continued to experience a sustained benefit; Aimovig maintained a consistent safety profile

EAST HANOVER, N.J., Oct. 3, 2020 /PRNewswire/ -- Novartis today announced that results reinforcing the long-term safety and efficacy profile of Aimovig® (erenumab-aooe) in patients with episodic migraine (EM) are being presented at the Migraine Trust Virtual Symposium. Results from the five-year, open-label treatment period of a Phase 2 study in episodic migraine prevention (NCT01952574) showed Aimovig helped patients achieve sustained reductions in monthly migraine days (MMD) and in use of acute migraine-specific medication (AMSM), such as triptans. Additionally, the safety profile was consistent with what was observed in the double-blind treatment phase of the study, with no increases in adverse event rates over five years of exposure.[1]

"These important data highlight the sustained efficacy, safety and tolerability profile of Aimovig, and provide crucial information for patients and doctors managing migraine," said Dr. Messoud Ashina, Professor of Neurology in the Faculty of Health and Medical Sciences at the University of Copenhagen. "The study reinforces the potential of Aimovig to reduce monthly migraine days over the long term for people living with this debilitating, yet underdiagnosed disease. For my patients, more migraine-free days means they're able to get back to the things that are important to them, like spending more time with family and friends, and being able to go to work."[1-4]

The five-year, open-label treatment phase enrolled 383 patients with episodic migraine who completed a 12-week double-blind, placebo-controlled treatment period (DBTP).[1] Among the 216 patients who completed the open-label treatment phase, there was an average MMD reduction of 5.3 days from the DBTP baseline of 8.7 days.[1] By the end of the study, patients who used AMSM to treat their migraine headaches experienced an average reduction in AMSM use of 4.4 days from the DBTP baseline of 6.2 days.[1] The most common side effects were nasopharyngitis, upper respiratory tract infection and influenza.[1]

"These long-term results signify a big step for people affected by this debilitating neurological disease, many of whom live in dread of the next attack,[3] and demonstrate progress for the millions of patients who may be candidates for preventive migraine treatment,"[2,5,6] said Victor Bultó, President, Novartis Pharmaceuticals Corporation. "As the first FDA-approved treatment and most prescribed preventive therapy in the calcitonin gene-related peptide class of medications, Aimovig represents Novartis' strong heritage and ongoing commitment to research and development to better support patients."[7,8]

Additional studies highlighting Aimovig will be presented at the Migraine Trust Virtual Symposium, including interim results of the LIBERTY open-label extension study as well as efficacy and safety results of Aimovig in the EMPOwER study. These studies reinforce the efficacy and safety profile of Aimovig for patients of various backgrounds across the episodic migraine spectrum.

- Interim two-year results of the open-label extension study of the LIBERTY study (NCT03096834) showed sustained efficacy and no increases in adverse events rates for patients with episodic migraine taking Aimovig who failed 2-4 prior preventive treatments.[9]
- Results of the Phase 3 EMPOwER study (NCT03333109) highlighted the efficacy and safety of Aimovig in adult patients with episodic migraine from Asia, the Middle East and Latin America.[10,11]

About the Open Label Extension Phase of the Phase 2 Study in Episodic Migraine Prevention (NCT01952574)

After a 12-week randomized, double-blind, placebo-controlled period, 383 eligible adult patients with episodic migraine (defined in the trial as 4 to 14 migraine days and less than 15 headache days per month at baseline), were enrolled in the open-label treatment phase.[1,12,13] All patients initially received 70 mg Aimovig monthly, with 250 patients increasing their dosage to 140 mg monthly after a protocol amendment to assess long-term safety of the higher dose.[1,12] Safety and tolerability were assessed by monitoring adverse events, electrocardiograms, laboratory assessments and vital signs.[1]

No new safety signals or increases in adverse event rates were observed over five years of exposure with Aimovig as compared to the DBTP, in which the safety and tolerability profile of Aimovig were in line with other clinical trial data.[1]

About Aimovig® (erenumab-aooe)

Aimovig, co-marketed in the U.S. by Amgen and Novartis, is the first and only FDA and EMA-approved migraine preventive treatment that targets the calcitonin gene-related peptide (CGRP) receptor, which is associated with migraine.[8,14] Aimovig has been studied in several large global, randomized, double-blind, placebo-controlled studies to assess its efficacy and safety in migraine prevention.[15,16] Aimovig is self-administered once monthly via the easy-to-use SureClick® autoinjector, without a required loading dose.[16] More than 3,000 patients participated in registrational trials of Aimovig across four placebo-controlled Phase 2 and Phase 3 clinical studies and their open-label extensions.[1,9,10,15,16]

Aimovig is also being evaluated through CATALYST, a comprehensive evidence generation program initiated by Amgen and Novartis that includes over 7,500 patients across 14 ongoing clinical trials and a robust assessment of real-world evidence. Spanning over 39 countries globally, CATALYST clinical trials will explore the role of Aimovig in comparative studies, assessing impact on novel migraine outcomes, understanding predictive biomarkers and expanding Aimovig's use in additional study populations. To date, more than 440,000 patients across 44 countries worldwide have been prescribed Aimovig for the preventive treatment of migraine in adults.[18]

AIMOVIG INDICATION

Aimovig® (erenumab-aooe) is indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

Contraindication: Aimovig® is contraindicated in patients with serious hypersensitivity to erenumab-aooe or to any of the excipients. Reactions have included anaphylaxis and angioedema.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, angioedema, and anaphylaxis, have been reported with Aimovig® in post marketing experience. Most reactions were not serious and occurred within hours of administration, although some occurred more than one week after administration. If a serious or severe reaction occurs, discontinue Aimovig® and initiate appropriate therapy.

Constipation with Serious Complications: Constipation with serious complications has been reported following the use of Aimovig® in the postmarketing setting. There were cases that required hospitalization, including cases where surgery was necessary. The onset of constipation was reported after the first dose in a majority of these cases, but patients also reported later on in treatment. Aimovig® was discontinued in most reported cases. Constipation was one of the most common (up to 3%) adverse reactions reported in clinical studies.

Monitor patients treated with Aimovig® for severe constipation and manage as clinically appropriate. Concurrent use of medications associated with decreased gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

Hypertension: Development of hypertension and worsening of pre-existing hypertension have been reported following the use of Aimovig® in the postmarketing setting. Many of the patients had pre-existing hypertension or risk factors for hypertension. There were cases requiring pharmacological treatment and, in some cases, hospitalization. Hypertension may occur at any time during treatment but was most frequently reported within seven days of dose administration. In the majority of the cases, the onset or worsening of hypertension was reported after the first dose. Aimovig® was discontinued in many of the reported cases.

Monitor patients treated with Aimovig® for new-onset hypertension, or worsening of pre-existing hypertension, and consider whether discontinuation of Aimovig® is warranted if evaluation fails to establish an alternative etiology.

Adverse Reactions: 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 see Aimovig® full Prescribing Information.

About Migraine

People with frequent migraine attacks may lose more than half their life to migraine.[12] One attack could last up to three days.[12] 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.[3,19] The 2017 Global Burden of Disease Study ranks migraine among the top 10 causes of years lived with disability worldwide.[20] Migraine is associated with personal and societal burdens of pain, disability and financial cost, and it remains under-recognized and under-treated.[2,4]

About 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).[8] In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the U.S. For the migraine programs, Amgen retains exclusive commercialization rights in the U.S. (other than for Aimovig as described above) and Japan, and Novartis has exclusive commercialization rights in Europe, Canada and rest of 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.

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of 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 employs about 15,000 people in the United States. For more information, please visit https://www.novartis.us.

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