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Market Access, Nordics at Novartis Pharmace...

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Novartis just received EU approval for a new migraine treatment!

Se översättning

designed for migraine prevention

JUL 30 2018

- Patients on Aimovig (erenumab) in clinical trials reported consistent and sustained migraine prevention, with many experiencing a 50% or more reduction in monthly migraine days; safety and tolerability were similar to placebo¹⁻³
- Migraine is the third leading cause of disability in people under 50, leading to severe disruption to the personal and professional lives of millions of sufferers. It is estimated to cost up to €27 billion per year in Europe alone^{4,5}
- Aimovig is the first and only approved migraine prevention treatment designed specifically to block the calcitonin gene-related peptide receptor (CGRP-R), which plays a critical role in migraine

Feature



Impact of Migraine Infographic

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Basel, [month day], 2018 – Novartis announced today that the European Commission (EC) approved Aimovig® (erenumab) for the prevention of migraine in adults experiencing four or more migraine days per month. Aimovig is the first and only treatment specifically designed for migraine prevention to be approved in the European Union, Switzerland, the US and Australia. It works by blocking a receptor called the calcitonin gene-related peptide receptor (CGRP-R) which plays a critical role in mediating the incapacitating pain of migraine. In the extensive clinical program of 2,600 patients, those on Aimovig experienced significant reductions in their number of migraine days per month, with a safety and tolerability profile similar to placebo¹⁻³. Aimovig can be self-administered or administered by another trained person every four weeks with the SureClick® autoinjector pen, an established device

Novartis marks a new era for migraine patients with the EU approval of Aimovig®,...

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Novartis marks a new era for migraine patients with the EU approval of Aimovig®, a first-of-its-kind treatment specifically designed for migraine prevention

- *Patients on Aimovig (erenumab) in clinical trials reported consistent and sustained migraine prevention, with many experiencing a 50% or more reduction in monthly migraine days; safety and tolerability were similar to placebo¹⁻³*
- *Migraine is the third leading cause of disability in people under 50, leading to severe disruption to the personal and professional lives of millions of sufferers; it is estimated to cost up to €27 billion per year in Europe alone^{4,5}*
- *Aimovig is the first and only approved migraine prevention treatment designed specifically to block the calcitonin gene-related peptide receptor (CGRP-R), which plays a critical role in migraine*

Basel, July 30, 2018 – Novartis announced today that the European Commission (EC) approved Aimovig® (erenumab) for the prevention of migraine in adults experiencing four or more migraine days per month. Aimovig is the first and only treatment specifically designed for migraine prevention to be approved in the European Union, Switzerland, the US and Australia. It works by blocking a receptor called the calcitonin gene-related peptide receptor (CGRP-R) which plays a critical role in mediating the incapacitating pain of migraine. In the extensive clinical program of 2,600 patients, those on Aimovig experienced significant reductions in their number of migraine days per month, with a safety and tolerability profile similar to placebo¹⁻³. Aimovig can be self-administered or administered by another trained person every four weeks with the SureClick® autoinjector pen, an established device commonly used for a range of different conditions.

“Migraine matters. It is a painful, highly disruptive neurological disease that affects all aspects of life, from going to work to spending time with family and friends,” said Patrick Little, President of the European Migraine and Headache Alliance. “A treatment specifically designed for migraine prevention is a much-welcomed innovation and could transform lives of patients for whom current therapies do not work or are not well tolerated.”

Aimovig showed efficacy even in a difficult-to-treat population. It is the only CGRP-R pathway therapy specifically studied in patients who had failed on two to four previous treatments commonly used for migraine prevention⁶. Furthermore, in an interim analysis from a five year open label extension (OLE) in episodic migraine, it was demonstrated that more than one in four (26%), patients taking Aimovig 70 mg, who were still enrolled and assessed for migraine over month fifteen, were completely migraine free⁷.

“Erenumab heralds a new era in clinical practice, bringing both a targeted mechanism for prevention and a deep understanding of migraine, which we have never had before,” said

Peter Goadsby, M.D., Ph.D., FRCP, Director, NIHR-Wellcome Trust King's Clinical Research Facility and Professor of Neurology at King's College London. "We will see sustained relief from migraine for many of those who suffer with this debilitating disease."

"Today's approval is groundbreaking for people living with migraine, their families and doctors" said Paul Hudson, CEO Novartis Pharmaceuticals. "In clinical trials, Aimovig has consistently shown to be effective in preventing migraine and bringing relief from the grip of this disease. We are proud to be the first to reimagine migraine prevention and we are committed to ensuring Aimovig's availability for those who could benefit from it. We are launching a tailored post-approval access program and are exploring a number of innovative reimbursement and access approaches, including paying only for patients who respond well to treatment."

A post-approval access program has been opened to provide Aimovig in countries where the local regulations allow provision of unapproved or yet to be reimbursed therapies. Support programs are also being developed for eligible patients in line with local regulations that include personalized services, information and resources to support them as they begin their treatment with Aimovig.

The EMA decision is applicable to all 28 European Union member states plus Iceland, Norway and Liechtenstein. Aimovig (erenumab-aooe) received U.S. FDA approval for the preventive treatment of migraine in adults on May 17, 2018. Aimovig received Swissmedic approval in Switzerland on July 13, 2018 and Australian TGA registration on July 3, 2018. Additional regulatory filings are underway with other health authorities worldwide.

About Aimovig® (erenumab)

Aimovig is the only EMA, Swissmedic, Australian TGA and FDA-approved migraine prevention treatment designed specifically to block the calcitonin gene related peptide receptor (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, 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 disease⁸. 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 odors⁹. Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society¹⁰. It has a profound and limiting impact on an individual's abilities to carry out everyday tasks and was reported by the World Health Organization to be one of the top 10 causes of years lived with disability for men and women⁴. It remains under-recognized and under-treated^{10,11}. Existing preventive therapies have been repurposed from other indications and are often associated with poor tolerability and lack of efficacy, with high discontinuation rates among patients¹².

We "Get" Migraine - About Novartis' Commitment to People Living with Migraine

Through support and education, we aim to challenge public perception of migraine, assist people in getting appropriate treatment and facilitate informed communication among people

with migraine and with those who live and work with them, including co-workers and employers.

As an employer, Novartis is also committed to supporting its associates living with migraine. The Migraine Care program is a pilot program created by Novartis, in collaboration with patient groups and leading experts in neurology, telemedicine and digital, to provide a complimentary service for all Swiss based Novartis associates living with migraine to improve their quality of life. The program aims to raise awareness of migraine in the workplace and provide free coaching to Novartis associates living with migraine to empower them in the management of the disease. Novartis is exploring opportunities to work with other employers who are interested in supporting their employees and family members living with migraine.

Novartis is also committed to working with the migraine community around the world to discover new ways to improve care for people living with the disease. Novartis and the European Migraine and Headache Alliance collaborated to launch the *My Migraine Voice* survey, a global survey designed to assess the worldwide migraine burden from the patient's perspective¹³. Data was collected from 11, 266 adults via a 30-minute online questionnaire fielded in 31 countries between September 2017 and February 2018. The survey questions covered the social, economic and emotional impact of the disease, the real-life experience of an individual living with migraine and their journey through the healthcare system and employment environment¹³.

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 U.S. 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.

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, spinal muscular atrophy 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," "can," "will," "could," "new era," "groundbreaking," "exploring," "look forward," "committed," "commitment," "investigational," "pipeline," "launch," "launching," "ongoing," "promising," 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 the post-approval access program or the other innovative reimbursement and access approaches will achieve any or all of their intended goals and objectives, or be commercially successful. Neither 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, the collaboration with Amgen, and the post-approval access program 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

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, 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 125,000 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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