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### World's first migraine-specific prevention treatment now available in Singapore as Health Sciences Authority approves Novartis Aimovig®

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## World's first migraine-specific prevention treatment now available in Singapore as Health Sciences Authority approves Novartis Aimovig®

- Close to 1 in 10 of the Singapore population suffers from migraine, a neurological condition that ranks 4th on the list of top 10 disorders causing years lived with disability for the Singapore population (ii)
- Aimovig is the world's first migraine-specific prevention treatment developed specifically to block the receptor which plays a critical role in migraine
- Around 1 in 2 patients on Aimovig (erenumab) in clinical trials reported consistent and sustained migraine prevention, with migraine days reduced by half each month. Treatment is well tolerated with no serious side effects (iii,iv,v)

**Singapore, November 22, 2018** – Novartis announced that the Health Sciences Authority (HSA) has approved Aimovig® (erenumab) in Singapore for the prevention of migraine in adults. Aimovig is the world's first treatment of its kind designed to block the receptor called calcitonin gene-related peptide receptor (CGRP-R) which plays a critical role in transmitting pain signals associated with migraine.

The approval follows the results from an extensive clinical program involving 2,600 patients where Aimovig showed consistent and sustained effect in migraine prevention. Around 1 in 2 patients were relieved from migraine days by half, each month (i, ii, iii). Its efficacy is evident even in a difficult-to-treat population – patients who had failed on two to four previous treatments commonly used for migraine prevention (vii).

#### Migraine is a debilitating neurological condition - not just a headache

Migraine is a debilitating neurological condition characterized by recurrent attacks of moderate to severe head pain that is typically pulsating, often unilateral (one-sided) and associated with nausea, vomiting and sensitivity to light, sound and odors.(viii) Migraine is more common in adults between 25 and 45 years of age, with a higher prevalence in women (i,ix). In Singapore, migraine ranks 4th on the list of top 10 most disabling health problems (ii).

"A migraine episode can last from a few hours to more than a day and many patients are unable to function at their full potential at work or school. When attacks are frequent, they impair the patients' quality of life and many lead inhibiting lifestyles for fear of triggering the next attack," said Dr Jonathan Jia Yuan Ong, President of the Headache Society of Singapore and Consultant, Division of Neurology, National University Hospital. The outpatient referral clinic for headache disorders at National University Hospital sees an estimated 1,250 new migraine sufferers each year.

Up to 67% of migraine patients suffer some degree of burden and compromises to various aspects of their life such as education, career, personal relationships, family life and social activities x. More than the economic costs associated with missed work or school and impaired work performance, migraine also takes an

emotional toll on patients. 1 in 2 patients in Singapore would experience worsened anxiety, insomnia and/or mood swings during a migraine episode.

Novartis has launched the #AheadofPain Facebook channel to raise awareness and bring help to people affected by migraine with inspirational patient stories and educational content such as tips on living and coping with a migraine. This platform also serves to reach those who live and work with migraine patients. There will be a three-part video series – the first of which is now LIVE on #AheadofPain Facebook page, with the rest rolling out in the next few months.

"Despite its prevalence and disease burden, migraine is an under-diagnosed and under-treated condition that is often mistaken as just a headache. Novartis is the first company to reimagine migraine with a treatment that has been specifically designed for migraine prevention. We remain committed to supporting patients through the #AheadofPain educational campaign that will elevate the understanding and awareness of this neurological condition in Singapore. Together with informed counseling, appropriate lifestyle management and preventive treatment, it is possible to improve the patients' quality of life," said Celine Landie, Managing Director, Novartis Singapore and Asian Emerging Countries.

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.

Aimovig is the first drug of its kind approved for migraine prevention in Singapore, the European Union, Switzerland, the US and Australia. Additional regulatory filings are underway with other health authorities worldwide.

#### About Aimovig® (erenumab)

Aimovig is an HSA, 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 injection site reactions, constipation, muscle spasm and itchy skin.

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 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 Japan, and Novartis has exclusive 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).

#### **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 124,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <u>http://www.novartis.com</u>

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x Novartis data on file, Singapore migraine research 2018

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