

Novartis expands global collaboration with Amgen to commercialize first-in-class AMG 334 (erenumab) program in migraine prevention in the U.S. and Canada

Apr 27, 2017

- Novartis and Amgen to co-commercialize AMG 334 (erenumab) in the U.S.; Novartis to gain exclusive rights in Canada
- Novartis retains commercial rights in rest of world; Amgen retains commercial rights in Japan
- Companies to combine capabilities and leverage Novartis strong and established neuroscience presence in the U.S. and across the globe to maximize launch of AMG 334 (erenumab)

East Hanover, NJ, April 24, 2017 – Novartis today announced an expanded commercialization agreement with Amgen for AMG 334 (erenumab), which is being investigated for the prevention of migraine. This agreement builds on a 2015 global collaboration between Novartis and Amgen, and leverages almost 70 years of Novartis experience in neuroscience to more effectively reach people with migraine. Novartis and Amgen will co-commercialize AMG 334 (erenumab) in the U.S. Novartis will retain exclusive rights to commercialize the drug in rest of world and will gain commercialization rights in Canada. Amgen retains exclusive commercialization rights in Japan. The companies will continue global co-development.

AMG 334 (erenumab) is a fully human monoclonal antibody specifically designed for the prevention of migraine. It targets and blocks the Calcitonin Gene-Related Peptide (CGRP) receptor, believed to play a critical role in mediating the incapacitating pain of migraine.¹ Positive results from a Phase II study and two Phase III studies of AMG 334 (erenumab) in migraine prevention were announced in 2016. In these studies, once-monthly subcutaneous AMG 334 (erenumab) significantly reduced monthly migraine days versus placebo and demonstrated a safety profile comparable to placebo.^{2,3,4} Detailed results from the Phase III studies are being presented at the annual meeting of the American Academy of Neurology and submitted for publication. These data will help support discussions with regulatory agencies, with filing anticipated in the second quarter of 2017.

“Migraine is a debilitating neurological disease associated with significant personal, economic, and societal burden. There is an urgent need for effective and well-tolerated preventive treatments that positively impact the lives of people with migraine,” said Paul Hudson, Chief Executive Officer, Novartis Pharmaceuticals. “We are excited to expand our collaboration with Amgen. We look forward to combining capabilities and leveraging our strong heritage in neuroscience in the U.S. and Canada to bring erenumab to more patients in need, as fast as we can.”

Under the terms of the agreement, Amgen will receive milestone payments from Novartis, expected to begin in 2017. Novartis will share U.S. commercialization costs with Amgen. Amgen will book sales of AMG 334 (erenumab) in the U.S., and will pay a royalty to Novartis on net sales in the U.S. Novartis will book sales in rest of the world, excluding Japan, and will pay Amgen royalties on the net sales in those countries. Amgen will book sales in Japan, since it will remain an exclusive territory for the company. Novartis will assume agreed upon remaining global development costs up to a cap and share global development costs thereafter.

The agreement is an expansion of a global collaboration with Amgen announced in August 2015 in neuroscience, involving joint development and commercialization of pioneering treatments in the field of Alzheimer's disease and migraine.⁵

About AMG 334 (erenumab)

AMG 334 (erenumab) is a fully human monoclonal antibody specifically designed to target and block the Calcitonin Gene-Related Peptide (CGRP) receptor, believed to play a critical role in mediating the incapacitating pain of migraine.¹ AMG 334 (erenumab) has been studied in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention. Following the initial Phase II dose finding study, the efficacy of AMG 334 (erenumab) in migraine prevention has been shown in a Phase II trial and two Phase III trials. The safety profile of AMG 334 (erenumab) in these studies was comparable to placebo.^{2,3,4}

About Migraine

Migraine is a distinct neurological disease.⁶ 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.⁷ Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society.⁸ It has a profound and limiting impact on an individual's abilities to carry out everyday tasks, and was declared by the World Health Organization to be one of the top 10 causes of years lived with disability for men and women.⁹ It remains under-recognized and under-treated.^{8,10} Existing preventive therapies have been repurposed from other indications and are often associated with poor tolerability and lack of efficacy, which lead to increasing discontinuation rates and dissatisfaction among patients.¹¹

About the Amgen and Novartis Neuroscience Collaboration

In August 2015, Novartis entered into a global collaboration with Amgen to jointly develop and commercialize pioneering neuroscience treatments in the field of Alzheimer's disease (AD) and migraine. The companies are partnering in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD. Novartis' oral therapy CNP520 (currently in a Phase II/III study for AD) will be the lead molecule and further compounds from both companies' pre-clinical BACE inhibitor programs may be considered as novel follow-on molecules. The 2015 collaboration also focuses on innovative investigational Amgen drugs in the migraine field, including AMG 334 (erenumab) in migraine prevention and AMG 301 (currently in a Phase I study for migraine).

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 (AD), Parkinson's disease, Epilepsy and Attention Deficit Hyperactivity Disorder, and have a promising pipeline in MS, AD, migraine and specialty neurology (e.g. neuropathic pain).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “to co-commercialize,” “to gain,” “to combine,” “launch,” “being investigated,” “builds on,” “will,” “believed to,” “submitted,” “anticipated,” “excited,” “look forward,” “expected,” “pioneering,” “may,” “investigational,” “ongoing,” “commitment,” “pipeline,” or similar terms, or by express or implied discussions regarding potential marketing approvals for AMG 334, CNP520, AMG 301, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the collaboration, potential new indications or labeling for products in the Novartis Neuroscience portfolio, or regarding potential future revenues from such investigational compounds and products, and potential future revenues from the collaboration with Amgen. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 AMG 334, CNP520, AMG 301, other BACE inhibitors of Novartis and Amgen, or other investigational compounds of Novartis and Amgen subject to the collaboration will be submitted or approved for sale 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 any product in the Novartis Neuroscience portfolio will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that AMG 334, CNP520, AMG 301, any of the other investigational compounds subject to the collaboration with Amgen, or any product in the Novartis Neuroscience portfolio will be commercially successful in the future. In particular, management's expectations regarding such investigational compounds and 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; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing and reimbursement pressures; safety, quality or manufacturing issues, 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 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com> 3/5

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>

For Novartis multimedia content, please visit www.novartis.com/news/media-library

For questions about the site or required registration, please contact media.relations@novartis.com

References

1. Bigal ME et al. Calcitonin Gene-Related Peptide (CGRP) and Migraine Current Understanding and State of Development. *Headache*. 2013;53(8):1230-1244.
2. Novartis presents new positive data at EHMTIC showing AMG 334 significantly reduces monthly migraine days in chronic migraine. <https://www.novartis.com/news/media-releases/novartis-presents-new-positive-data-ehmtic-showing-amg-334-significantly-reduces>. Accessed April 2017.
3. Novartis announces Phase III study shows AMG 334 significantly reduces monthly migraine data in people with episodic migraine. <https://www.novartis.com/news/media-releases/novartis-announces-phase-iii-study-shows-amg-334-significantly-reduces-monthly>. Accessed April 2017.
4. Novartis announces AMG 334 significantly reduces monthly migraine days in second pivotal Phase III episodic migraine study. <https://www.novartis.com/news/media-releases/novartis-announces-amg-334-significantly-reduces-monthly-migraine-days-second>. Accessed April 2017.
5. [Novartis announces global partnership with Amgen to develop and commercialize pioneering neuroscience treatments](https://www.novartis.com/news/media-releases/novartis-announces-global-partnership-with-amgen-to-develop-and-commercialize-pioneering-neuroscience-treatments). <https://www.novartis.com/news/media-releases/novartis-announces-global-....>. Accessed April 2017.
6. Migraine Research Foundation. Migraine Fact Sheet. 2015. <http://www.migraineresearchfoundation.org/fact-sheet.html>. Accessed April 2017.
7. National Institute for Neurological Disorders and Stroke. <https://www.ninds.nih.gov/Disorders/All-Disorders/Migraine-Information-...> (link is external). Accessed April 2017.
8. World Health Organization. Headache disorders. <http://www.who.int/mediacentre/factsheets/fs277/en/> (link is external). Accessed October 2016.
9. World Health Organization. Estimates for 2000-2012. Disease Burden. 2012.
10. Diamond S et al. Patterns of Diagnosis and Acute and Preventive Treatment for Migraine in the United States: Results from the American Migraine Prevalence and Prevention Study. *Headache*. 2007;47(3):355-63.
11. Hepp Z, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. *Cephalalgia*. 2015; 35(6):478-88.

###

Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff

Christina Zoppi

Novartis Global Media Relations Novartis Communications & Patient Relations

1-212-830-2408 (direct)

1-862-778-9179 (direct)

1-646-438-4335 (mobile)

1-862-345-4140 (mobile)

eric.althoff@novartis.com

christina.zoppi@novartis.com

Source URL: <https://qa1.novartis.us/us-en/news/media-releases/novartis-expands-global-collaboration-amgen-commercialize-first-class-amg-334-erenumab-program-migraine-prevention-us-and-canada>

List of links present in page

1. <https://qa1.novartis.us/us-en/us-en/news/media-releases/novartis-expands-global-collaboration-amgen-commercialize-first-class-amg-334-erenumab-program-migraine-prevention-us-and-canada>
2. <http://www.novartis.com/>
3. <http://twitter.com/novartis>
4. <http://www.novartis.com/news/media-library>
5. <mailto:media.relations@novartis.com>
6. <https://www.novartis.com/news/media-releases/novartis-presents-new-positive-data-ehmtic-showing-amg-334-significantly-reduces.%20Accessed%20April%202017>
7. <https://www.novartis.com/news/media-releases/novartis-announces-phase-iii-study-shows-amg-334-significantly-reduces-monthly>
8. <https://www.novartis.com/news/media-releases/novartis-announces-amg-334-significantly-reduces-monthly-migraine-days-second>
9. <https://www.novartis.com/news/media-releases/novartis-announces-global-partnership-amgen-develop-and-commercialize-pioneering>
10. <https://www.novartis.com/news/media-releases/novartis-announces-global-partnership-amgen-develop-and-commercialize-pioneering>
11. <http://www.migraineresearchfoundation.org/fact-sheet.html>
12. <https://www.ninds.nih.gov/Disorders/All-Disorders/Migraine-Information-Page>
13. <http://www.who.int/mediacentre/factsheets/fs277/en/>
14. <mailto:media.relations@novartis.com>
15. <mailto:eric.althoff@novartis.com>
16. <mailto:christina.zoppi@novartis.com>