Novartis reports erenumab met all primary and secondary endpoints in unique Phase IIIb study in episodic migraine patients who have failed multiple prior preventive treatments

- **LIBERTY** is the first migraine prevention trial of its kind conducted specifically in patients who have tried multiple therapies without success, and are in need of additional treatment options

- The trial met its primary endpoint of percentage of patients on erenumab (AMG 334) achieving at least a 50% reduction of migraine days versus placebo, and all secondary endpoints

- Statistically significant and clinically meaningful results add to the consistent efficacy and placebo-like safety profile of erenumab seen across the spectrum of migraine, even in more difficult-to-treat patients

**Basel, January 22, 2018** – Novartis today announced positive results from the Phase IIIb LIBERTY study assessing the efficacy and safety of erenumab (AMG 334) 140mg in patients with episodic migraine who had experienced two to four previous preventive treatment failures, due to lack of efficacy or intolerable side effects. The study met its primary endpoint, with significantly more patients taking erenumab experiencing at least a 50% reduction from baseline in their monthly migraine days as compared to placebo. LIBERTY also met all secondary endpoints including: reduction of monthly migraine days, reduction in days needing acute (rescue) medication, improvement in scores on the Migraine Physical Function Impact Diary (MPFID) tool, and 75% and 100% responder rates (number of patients experiencing at least a 75% or 100% reduction in monthly migraine days compared to placebo.) The safety data are consistent with previous studies of erenumab to date, showing a placebo-like safety profile. Full data will be presented at an upcoming scientific meeting.

“The LIBERTY trial is the only Phase IIIb anti-CGRP study to demonstrate safety and efficacy in patients who have repeatedly failed other preventive treatments,” said Danny Bar-Zohar, Global Head of Neuroscience Development for Novartis. “The results add to the consistent body of evidence for erenumab across the full spectrum of migraine patients, from those trying preventive medication for the first time through to those who have failed multiple therapies and have been suffering for years. We look forward to making erenumab, the first targeted preventive option specifically designed for migraine, available to patients as soon as possible.”

Erenumab is the only investigational fully human monoclonal antibody designed to selectively block the calcitonin gene-related peptide (CGRP) receptor, which plays a critical role in migraine activation. Currently available preventive treatments for migraine have generally been repurposed from other therapeutic areas and are often associated with poor tolerability and lack of efficacy.

The safety, efficacy and tolerability of erenumab have been assessed in clinical studies involving more than 3,000 patients, including an ongoing open-label extension up to five years.
in duration. Erenumab was the first investigational therapy targeting the CGRP pathway to have received Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulatory filing acceptance. If approved, it will be administered once-monthly using a self-injection device. Subject to approval, Novartis and Amgen will co-commercialize erenumab 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 LIBERTY
LIBERTY (NCT03096834) is a Phase IIIb, multicenter, randomized 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in patients with episodic migraine (defined in the trial as four to 14 migraine days per month at baseline) who have failed two to four prior preventive treatments for migraine. In the study, 246 participants were randomized to receive erenumab 140mg or placebo during the 12-week double-blind treatment phase. The primary endpoint was the percentage of patients with at least 50% reduction of monthly migraine days from baseline over the last four weeks of the double-blind treatment phase of the study (weeks 9-12)². The trial includes an ongoing 52 week open-label extension study.

Secondary endpoints assessed during the same time period included: change from baseline in monthly migraine days, change from baseline in the number of monthly acute migraine-specific medication treatment days, change from baseline in the Migraine Physical Function Impact Diary (MPFID) physical impairment and impact on everyday activities domain scores. The MPFID is a scale developed to measure these two domains. It has been validated in line with US Food and Drug Administration Patient Reported Outcomes Guidance³. Percentages of patients with a 75% response rate and 100% response rate to erenumab, and safety and tolerability were also assessed as secondary endpoints.

About erenumab (AMG 334)
Erenumab (AMG 334) is the only investigational treatment specifically designed to prevent migraine by blocking the CGRP receptor, which plays an important role in migraine activation. Erenumab 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 clinical trial program across the four placebo-controlled Phase II and Phase III clinical studies and their open-label extensions.

About Migraine
Migraine is a distinct neurological disease. 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. Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society. 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. It remains under-recognized and under-treated. 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 patients.

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 and Alzheimer's disease. The collaboration focuses on investigational Amgen drugs in the migraine field, including erenumab (Biologics License Application submitted to FDA in May 2017) and AMG 301 (currently in Phase 2 development). In April 2017, the collaboration was expanded to include co-commercialization of erenumab in the U.S. For the migraine programs, Amgen retains exclusive commercialization rights in the U.S. (other than for erenumab as described as above) and Japan, and Novartis has exclusive commercialization rights in Europe, Canada.
and rest of the 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 3 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.

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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,” “expect,” “anticipate,” “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 AMG 334 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 AMG 334 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 AMG 334 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, 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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues; potential or actual data security and data privacy 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
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 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 121,000 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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