Novartis announces global partnership with Amgen to develop and commercialize pioneering neuroscience treatments

- The companies plan to co-develop and co-commercialize a BACE inhibitor program in Alzheimer’s Disease (AD); Novartis’ oral therapy CNP520 will be the lead molecule
- Novartis and Amgen also plan to co-develop and co-commercialize Amgen’s migraine portfolio, including fully human monoclonal antibody AMG 334 with first phase III data expected in 2017
- Partnership reinforces Novartis’ continued commitment to developing and bringing innovative neuroscience treatment options to patients

Basel, September 1, 2015 – Novartis announced today that it has entered into a global collaboration with Amgen to commercialize and develop pioneering neuroscience treatments. The companies will partner in the development and commercialization of a BACE inhibitor program in Alzheimer’s Disease (AD). Novartis’ oral therapy CNP520 will be the lead molecule and further compounds from both company’s pre-clinical BACE inhibitor programs may be considered as follow-on molecules. The collaboration will also focus on new Amgen drugs in the migraine field, including phase III AMG 334 and phase I AMG 301. For the migraine program, Novartis will have global co-development rights and commercial rights outside the U.S., Canada, and Japan.

“This Novartis collaboration with Amgen highlights our clear commitment to neuroscience and to bring multiple, new targeted therapies to patients living with Alzheimer’s disease and migraine, where the unmet medical need remains high.” said David Epstein, Head of Novartis Pharmaceuticals.

Alzheimer’s Disease is an irreversible, progressive brain disease characterized by loss of memory and other cognitive abilities. Amyloid build-up is considered a key driver of the progressive damage of the nervous system in AD. CNP520 is an oral drug designed to prevent the production of different forms of amyloid and has the potential to prevent, slow or delay the symptoms associated with AD. It is currently in phase I/IIa trials. CNP520 is planned to be included in a pioneering prevention study in people with a genetic risk of developing AD, in collaboration with the Banner Alzheimer’s Institute.

Migraine is a severe headache condition affecting more than 10% of the population worldwide and a leading cause of disability. AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine. AMG 334 inhibits the activity of Calcitonin-Gene-Related-Peptide (CGRP) by targeting its receptor. CGRP is believed to play a key role in the development of migraine. AMG 334 is currently under evaluation in several large global, randomized, double-blind, placebo-controlled phase III trials to assess its safety and efficacy in migraine prevention. In addition to AMG 334, the migraine portfolio will include the development of AMG 301 and potentially another investigational compound of Amgen. AMG 301 is a monoclonal antibody being investigated in phase I trials for the prevention of migraine.
The partnership with Amgen follows two recent developments in the Novartis neuroscience portfolio aimed at complementing Novartis’ neuroscience presence and pipeline in, among others, multiple sclerosis, AD and neuromuscular diseases. In July 2015 Novartis acquired Spinifex Pharmaceuticals adding phase II compound EMA401 for the treatment of neuropathic pain to the portfolio. In August 2015 Novartis announced that it has entered into an agreement to acquire all remaining rights to Ofatumumab from GlaxoSmithKline plc (GSK) for relapsing-remitting multiple sclerosis (RRMS) and certain other autoimmune indications; closing of this transaction is subject to expiry of any waiting period under the US Hart-Scott-Rodino Act and other customary closing conditions.

Under the terms of the arrangement, Novartis and Amgen will share responsibilities for development and commercialization of the BACE inhibitor program. Amgen will pay an upfront payment and milestone payments as well as disproportional research and development costs for an agreed upon period followed by a 50/50 cost and profit share arrangement. For the compounds in the migraine field, Novartis receives global co-development rights and commercial rights outside the U.S., Canada and Japan to the investigative molecules in Amgen’s migraine portfolio. This includes AMG 334 in phase III and AMG 301 in phase I as well as an option to commercialize an additional early-stage Amgen molecule in these territories. Novartis will fund disproportional global R&D expenses for an agreed period on the migraine programs and will pay Amgen double-digit royalties on sales.

About Alzheimer’s
It is estimated that around 44 million people globally have Alzheimer’s or a related dementia. Alzheimer’s Disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills and, eventually even the ability to carry out the simplest tasks of daily living. In most people with Alzheimer’s, symptoms first appear after age 60. Alzheimer’s Disease is the most common cause of dementia among older people. Although treatment can help manage symptoms in some people, currently there is no cure for this devastating disease.

About Migraine
Migraine is a type of headache disorder that involves recurrent attacks of moderate to severe pain that is typically pulsating, often unilateral and often associated with nausea, vomiting and sensitivity to light, sound and odors. Headache disorders are underestimated, under-recognized and under-treated throughout the world and are associated with personal and societal burdens of pain, disability, damaged quality of life and financial cost. There is a significant need for tolerable and efficacious preventive medications for migraine as discontinuation rates for existing oral preventive medications are high.

About Novartis in Alzheimer’s Disease
Novartis has a strong commitment to the treatment and prevention of Alzheimer’s Dementia.

Exelon® Patch (rivastigmine transdermal system) is approved for the treatment of mild-to-moderate Alzheimer’s Disease (AD) dementia in more than 90 countries, including more than 20 countries where it is also approved for Parkinson’s disease dementia. Exelon Patch is also indicated for the treatment of patients with severe AD in 14 countries, including the US.

Novartis AD pipeline includes CNP520, an oral drug designed to prevent the production of different forms of amyloid that has the potential to prevent, slow or delay the symptoms associated with AD. It is currently in phase I/IIa trials. The pipeline also includes investigational compound CAD106. This is an anti-amyloid active immunotherapy which has completed phase IIa trials.
About collaboration with Banner Alzheimer’s Institute (BAI)
In collaboration with the Banner Alzheimer’s Institute (BAI), Novartis is conducting a pioneering prevention study. The study with Banner is part of a ground-breaking research program known as the Alzheimer’s Prevention Initiative and will involve more than 1,300 cognitively healthy adults, ages 60 to 75, with a genetic risk of developing symptoms of AD because they inherited two genetic copies of the apolipoprotein E epsilon 4 (APOE4) allele – one from each parent. About 2 percent of the world’s population has this genetic profile, which is strongly linked to late-onset AD. One in four people carries one copy of the APOE4 gene. Participants in the study will be given either CAD106 (not included in the collaboration with Amgen), CNP520, or placebo. Pending regulatory approval, the study is planned to start in late 2015/early 2016 in sites in North America and Europe.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "plan," "will," "expected," "commitment," "may," "under investigation," "under evaluation," "potentially," "investigational," "being investigated," "aimed," "subject to," "investigative," "pipeline," "pending," "planned," or similar terms, or by express or implied discussions regarding potential marketing approvals for CNP520, AMG 334, AMG 301, CAD106, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the partnership and collaboration, new indications or labeling for Exelon Patch, or regarding potential future revenues from such investigational compounds and products, and potential future revenues from the partnership and 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 CNP520, AMG 334, AMG 301, CAD106, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the partnership and collaboration will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that Exelon Patch 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 the partnership and 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 Exelon Patch or any of the investigational compounds subject to the partnership and collaboration with Amgen will be commercially successful in the future. In particular, management’s expectations regarding such investigational compounds and products, and the partnership and collaboration with Amgen could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected 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 pressures; unexpected safety issues; unexpected manufacturing or quality 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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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