Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

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Novartis, Amgen and Banner Alzheimer's Institute discontinue clinical program with BACE inhibitor CNP520 for Alzheimer's prevention

After review of clinical data from the Generation Program studies, the sponsors concluded that the potential benefit for participants taking CNP520 no longer outweighs the risk

Basel, July 11, 2019 – Novartis, Amgen and Banner Alzheimer's Institute today announced the decision to discontinue investigation of the BACE1 inhibitor CNP520 (umibecestat) in two pivotal Phase II/III studies in the Alzheimer's Prevention Initiative Generation Program. An assessment of unblinded data during a regular pre-planned review identified worsening in some measures of cognitive function. Given these findings, the sponsors concluded that the potential benefit for participants in the studies did not outweigh the risk.

John Tsai (M.D.), Head of Global Drug Development and Chief Medical Officer, said: "Novartis has a strong research focus and commitment to patients. As researchers we have to accept today's disappointing news as part of the search for innovative new treatments. We remain committed to advancing science in Alzheimer's disease and continue to seek future solutions for people with neurodegenerative conditions."

Alzheimer's is a complex disease and one of the largest challenges facing healthcare today. The Generation Program sponsors are grateful to the participants and their study partners and the medical community for their contributions to advancing Alzheimer's research.

CNP520 was being assessed for safety and efficacy in the prevention or delay of the onset of Alzheimer's in people at high risk for developing symptoms based on their age and genetic status. The study sponsors are informing investigators of the decision to discontinue the clinical program of CNP520 in Alzheimer's prevention, and advising that participants should stop taking the investigational treatment. The clinical investigators will contact participants to discuss what happens next, including follow-up appointments as appropriate.

The study sponsors intend to further assess and present the data at a future scientific venue. Dr. Tsai said: "Beyond presenting our analyses, we will go a step further and will also share our data with the scientific community, not only to contribute to the increasing body of knowledge in Alzheimer's research but to add value to ongoing discussions with governments, multilateral organizations, patient groups, pharmaceutical companies, and society, to ensure that we collectively address the public health challenges presented by this disease."

Novartis has a strong ongoing commitment to neuroscience and to bringing innovative treatments to patients with or at risk of developing neurological conditions where there is a high unmet need. We are committed to supporting patients and physicians in many disease areas, including Multiple Sclerosis (MS), migraine, Spinal Muscular Atrophy (SMA) and specialty neurological conditions. Our neuroscience pipeline remains robust with four molecules currently in clinical development, as well as early assets in Alzheimer's.

About the 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 Generation Program studies are sponsored by Novartis and Amgen, in collaboration with Banner Alzheimer's Institute. Novartis is the regulatory sponsor, while Amgen and Novartis are co-development partners.

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About Novartis
Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 105 000 people of more than 140 nationalities work at Novartis around the world. Find out more at **www.novartis.com**.

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Novartis Global External Communications
E-mail: media.relations@novartis.com

Antonio Ligi
Novartis Global External Communications
+41 79 723 3681 (mobile)
antonio.ligi@novartis.com

Gonzalo Linares
Global Drug Development Communications
+41 61 324 5117 (direct)
+41 79 386 7432 (mobile)
gonzalo.linares@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@novartis.com

Friedrich von Heyl
Novartis Global Pharma Communications
+41 61 324 8984(direct)
+41 79 749 0286 (mobile)
friedrich.vonheyl@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 862 778 3275
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 862 778 3258
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		