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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis announces new data from the first direct head-to-head trial to demonstrate superior efficacy of Gilenya® over Copaxone® in patients with relapsing remitting multiple sclerosis

- *Topline findings from ASSESS show adult relapsing remitting multiple sclerosis (RRMS) patients taking Gilenya (fingolimod) 0.5mg experienced significantly fewer relapses than patients on Copaxone (glatiramer acetate) 20mg*

- *Gilenya 0.5mg is the first and only disease modifying therapy to show superiority in reducing relapses vs Copaxone in a controlled, head-to-head trial*

- *Treatment discontinuations were overall more common in the Copaxone group due to adverse events and unsatisfactory therapeutic effects*

Basel, October 10, 2018 – Novartis announced today topline results from the Phase IIIb ASSESS study, which evaluated the efficacy and safety of oral, once daily Gilenya (fingolimod) 0.5mg and 0.25mg versus once daily subcutaneous injections of Copaxone (glatiramer acetate) 20mg in patients with relapsing remitting multiple sclerosis (RRMS). The data show that Gilenya 0.5mg met its primary endpoint of significantly reducing the annualized relapse rate (ARR) compared to Copaxone[1]. Treatment with Gilenya 0.5mg resulted in a 40.7% relative reduction in the rate of relapses over a period of one year, compared to Copaxone (ARR estimates of 0.153 vs. 0.258, respectively, p= 0.0138)[1]. Further initial findings showed adults taking Gilenya 0.25mg achieved a numerical risk reduction in relapses compared to the comparator, but did not reach statistical significance. The safety of Gilenya observed in ASSESS across both doses was consistent with the known safety profile of the drug, with overall more discontinuations due to adverse events and unsatisfactory treatment effects reported in the Copaxone group[1].

“ASSESS is the first controlled head-to-head study of a MS disease modifying therapy versus Copaxone to show superior efficacy in reducing relapses, a key measure of disease activity and a significant burden for patients,” said Bruce Cree, MD, PhD, MAS, George A. Zimmermann Endowed Professor in Multiple Sclerosis at the University of California San Francisco, and ASSESS Principal Study Investigator. “Head-to-head trials, such as ASSESS, are extremely important to help clinicians better understand the relative efficacy and safety of MS therapies, thereby making better-informed treatment decisions.”

“Gilenya reimagined MS care as the first oral treatment and is a testament to Novartis’ quest to stop MS,” said Danny Bar-Zohar, Global Head of Neuroscience Development, Novartis Pharmaceuticals. “The ASSESS data add to the robust body of evidence which show that Gilenya is a highly efficacious, cornerstone therapy in relapsing MS.”

Gilenya 0.5mg is a leading oral disease-modifying therapy, that has demonstrated high efficacy across multiple measures of disease activity in patients 10 years of age and through to adulthood. To date, Gilenya 0.5mg has been used to treat more than 255,000 patients worldwide[1]. Long-term experience has shown Gilenya treatment to be convenient for people

to incorporate into everyday life, leading to high treatment satisfaction, long-term persistence, and ultimately, improved long-term outcomes[2,3]. Gilenya 0.25mg is not approved for adults with RRMS.

Novartis will complete full analyses of the ASSESS data and intends to submit the full results to upcoming medical meetings and for peer-reviewed publication.

About the ASSESS Study
The ASSESS study (NCT01633112) is a Phase IIIb randomized, rater- and dose-blinded study to compare the safety and efficacy of Gilenya (fingolimod) 0.25mg and 0.5mg administered orally once-daily, with Copaxone (glatiramer acetate) 20mg administered via subcutaneous injections once-daily, in patients with RRMS over the course of one year.

Novartis initiated the ASSESS study in 2012 as part of a post-approval commitment to the US FDA. In agreement with the FDA, a total of 1,064 patients were enrolled into ASSESS, with 352, 370 and 342 patients randomized in Gilenya 0.5mg, Gilenya 0.25mg and Copaxone 20mg arms respectively.

About Multiple Sclerosis
Multiple sclerosis (MS) is a chronic disorder of the central nervous system (CNS) that disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss[4]. In adults, there are three main types of MS: relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS)[5]. Approximately 85% of people with MS have relapsing-remitting MS, where the immune system attacks healthy tissue[6]. In children, RRMS account for nearly all cases (approximately 98%)[7].

About Novartis in Multiple Sclerosis
The Novartis multiple sclerosis portfolio includes Gilenya® (fingolimod, an S1P modulator), which is indicated for relapsing forms of MS. In the United States, Gilenya is the first disease-modifying therapy approved for the treatment of children and adolescents 10 to less than 18 years of age with relapsing forms of multiple sclerosis (RMS). In September 2018, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended approval of Gilenya for the treatment of children and adolescents 10 to 17 years of age with relapsing remitting forms of multiple sclerosis (RRMS). The European Commission will review the CHMP opinion and is expected to deliver its final decision within three months.

Investigational compounds include siponimod (BAF312). Siponimod is an investigational, selective modulator of specific subtypes of the sphingosine-1-phosphate (S1P) receptor, and has the potential to delay progression and expand possibilities for patients with typical SPMS. Novartis initiated the submission of siponimod for US approval in SPMS in the first half of 2018, which was followed by filing with the EMA in September 2018 for EU approval. The file has been accepted by both agencies.

Our other investigational compound is ofatumumab (OMB157), a fully human monoclonal antibody in development for relapsing MS. Ofatumumab targets CD20, and is currently being investigated in two Phase III pivotal studies.

Extavia® (interferon beta-1b for subcutaneous injection) is approved in the US for the treatment of relapsing forms of MS. In Europe, Extavia is approved to treat people with relapsing-remitting MS, secondary progressive MS (SPMS) with active disease and people who have had a single clinical event suggestive of MS.

In the US, the Sandoz Division of Novartis markets Glatopa® (glatiramer acetate injection) 20 mg/mL and 40 mg/mL, generic versions of Teva's Copaxone®.

*Copaxone® is a registered trademark of Teva Pharmaceutical Industries Ltd.

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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 nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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