Breadth of data at ECTRIMS underpins Novartis’ relentless commitment to decoding the science of multiple sclerosis (MS) and decreasing the patient burden

- 33 abstracts from the leading MS portfolio include data for Gilenya® (fingolimod), and investigational drugs siponimod (BAF312) and ofatumumab (OMB157)

- New research will be presented on neurofilaments, a biomarker for MS that can be detected in the blood and could reimagine the way treatments are assessed in clinical trials

- MS portfolio underlines the company’s drive to identify the right approach for each patient, across all age groups and types of MS

Basel, October 10, 2018 – Novartis announced today it will present 33 scientific abstracts at the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) being held October 10-12, 2018 in Berlin, Germany. The presentations highlight the company’s efforts to advance the understanding of MS and showcase its broad portfolio which addresses different types of MS across patients of all ages.

The abstracts presented at ECTRIMS include studies on Gilenya® (fingolimod), a leading oral disease modifying therapy and the only relapsing MS treatment approved in the US for children 10 years of age through to adulthood. There will also be data for the investigational treatment siponimod (BAF312), the first and only oral drug to meaningfully delay disability progression in typical secondary progressive MS (SPMS) patients; and ofatumumab (OMB157), the first self-administered subcutaneous B-cell therapy for relapsing MS (RMS), which is currently in Phase III development.

Novartis will also present new data on neurofilaments, protein fragments that are found in the blood at elevated levels in MS patients when damage to neurons occurs. Today, it is possible to measure neurofilaments in the blood and there is growing evidence that demonstrates a strong correlation between their levels and key measures of MS disease activity. Utilizing blood neurofilaments as an easy-to-use biomarker for MS could transform clinical trials in the future and allow for disease monitoring in real time in routine clinical practice. Novartis is leading the field with 12 data analyses presented so far.

“At Novartis, we are working to ensure there is an effective treatment for every MS patient, regardless of their age or level of disability progression,” said Danny Bar-Zohar, Global Head, Neuroscience Development for Novartis. “We are committed to transform the lives of people living with MS and reimagining care by relentlessly confronting the disease from all angles.”

Highlights of the Novartis data include:
New research shows neurofilaments are good predictors of long-term clinical outcomes in MS: One study showed neurofilaments were effective in predicting long-term disability progression in patients with RRMS. In another, blood neurofilament light chain predicted brain atrophy in patients with PPMS and SPMS in placebo-controlled Phase III trials of fingolimod (INFORMS) and siponimod (EXPAND) respectively. A third study investigated the predictive value of neurofilaments for disease activity and drug response in pediatric MS patients, and the data suggest that they may be useful biomarkers in this population.

Long-term safety of siponimod in SPMS: New data showed that longer-term follow up treatment (up to six years) with siponimod 2 mg did not reveal any increase in incidence rates of adverse events or new safety findings. These results demonstrated siponimod could be a safe and effective treatment option for typical SPMS patients.

Baseline characteristics of patients in the fully enrolled ASCLEPIOS program with ofatumumab: Studies provide additional data on patients treated with ofatumumab, the first fully human anti-CD20 monoclonal antibody with a monthly self-administered subcutaneous dosing regimen tailored for MS. Two parallel Phase III trials are currently being conducted to evaluate its efficacy and safety versus teriflunomide in patients with relapsing multiple sclerosis (RMS).

About Multiple Sclerosis
Multiple sclerosis (MS) affects approximately 2.3 million people worldwide. 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.

The evolution of MS results in an increasing loss of both physical (e.g. walking) and cognitive (e.g. memory) function. In adults, there are three types of MS: relapsing-remitting MS, secondary progressive MS and primary progressive MS. Approximately 85 percent of people with MS have relapsing-remitting MS, where the immune system attacks healthy tissue. In children, RRMS accounts for nearly all cases (approximately 98 percent).

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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uncertainties inherent in research and development, including clinical trial results and
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Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission.
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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
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Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Angela Fiorin
Novartis Global Pharma Communications
+41 61 324 8631 (direct)
+41 79 752 6955 (mobile)
angela.fiorin@novartis.com

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

Central
Samir Shah +41 61 324 7944 Pierre-Michel Bringer +41 61 324 1065 Thomas Hungerbuehler +41 61 324 8425

North America
Richard Pulik +1 212 830 2448 Cory Twining +1 212 830 2417

Isabella Zinck +41 61 324 7188