Data at AAN showed Gilenya® high efficacy in achieving ‘no evidence of disease activity’ in previously-treated highly-active MS patients

- New FREEDOMS/FREEDOMS II sub-group analysis showed Gilenya-treated patients were six-times more likely to achieve ‘no evidence of disease activity (NEDA4)’ vs placebo

- NEDA4 is based on four key measures of relapsing MS (RMS): relapses, MRI lesions, MS-related brain shrinkage and disability progression

- Separate analysis from the entire TRANSFORMS study showed that RMS patients treated with Gilenya were twice as likely to achieve NEDA4 vs Avonex®

Basel, 21 April 2015 – Novartis announced today new analysis from the phase III FREEDOMS and FREEDOMS II trials presented at the 67th American Academy of Neurology (AAN) Annual Meeting in Washington, DC, USA. These data showed that previously-treated patients with highly-active relapsing multiple sclerosis (RMS) who were treated with Gilenya® (fingolimod) had a six-times greater likelihood of achieving ‘no evidence of disease activity’ across four key measures of disease activity compared to placebo over two years (odds ratio 6.35; 95% CI 3.02-13.35; p<0.0001). This is referred to as NEDA4 and is achieved when a patient with RMS has no relapses, no new MRI lesions, no MS-related brain shrinkage and no disability progression.

This analysis was the first time patients with highly-active RMS who had been treated in the previous year with an injectable therapy were assessed using the NEDA4 definition that includes brain shrinkage. Brain shrinkage is a marker of the widespread inflammatory (diffuse) damage in the central nervous system and is associated with accumulated loss of function. By using this updated NEDA4 definition, physicians are able to get a more complete picture of a patient’s disease and response to treatment, which is crucial to identify the optimal therapy to slow short- and long-term disease progression. This is especially important for people with highly-active RMS, who are at a greater risk of relapses and future loss of function, and may therefore require a different treatment approach.

“NEDA4 is a major step forward in assessing RMS progression, helping physicians to develop effective disease management and treatment strategies for their patients,” said Vasant Narasimhan, Global Head of Development at Novartis Pharmaceuticals. “These data confirm that Gilenya’s high efficacy across the four key measures is maintained in previously-treated highly-active RMS, and underscores the important role of Gilenya in the treatment of RMS patients.”

Separate analysis from the entire phase III TRANSFORMS study also confirmed that after one year of treatment, RMS patients on Gilenya were twice as likely to achieve NEDA4 compared to patients given Avonex® - interferon beta-1a i.m. injections (odds ratio 1.93; 95% CI 1.36-2.73; p=0.0002). The data provide further evidence of how Gilenya helps RMS patients achieve NEDA4 across four key measures of disease activity.
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. The evolution of MS results in an increasing loss of both physical and cognitive (e.g. memory) function. This has a substantial negative impact on the approximately 2.3 million people worldwide affected by MS, a disease that most often begins in early adulthood.

People with MS can be diagnosed with relapsing forms of MS (RMS), which include relapsing remitting MS (RRMS) and secondary progressive MS (SPMS), or with primary progressive MS (PPMS).

The loss of physical and cognitive function in RMS is driven by two types of damage that result in the loss of neurons and brain tissue - distinct inflammatory lesions (referred to as focal damage), and more widespread inflammatory neurodegenerative processes (referred to as diffuse damage). Focal damage results in the loss of brain tissue and can clinically present as relapses. Diffuse damage starts early in the disease, often goes unnoticed and is also associated with loss of brain tissue and accumulated loss of function.

About Gilenya
Gilenya is the only oral disease-modifying therapy (DMT) to impact the course of relapsing MS (RMS) with high efficacy across four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression. Gilenya is approved in the US for first-line treatment of relapsing forms of MS in adults.

In the EU, Gilenya is indicated for adult patients with highly-active relapsing remitting MS (RRMS) defined as either high disease activity despite treatment with at least one DMT, or rapidly evolving severe RRMS.

Gilenya targets both focal and diffuse CNS damage. It prevents cells that cause focal inflammation from reaching the brain (referred to as ‘peripheral’ action), but also enters the CNS and reduces the diffuse damage by preventing the activation of harmful cells residing in the CNS (referred to as ‘central action’). It is important to address both focal and diffuse damage in RMS to effectively impact disease activity and help preserve an individual’s functions.

The safety profile of Gilenya in RMS is well understood and based on substantial evidence from three major clinical trials and extensive real-world experience in more than 119,000 patients, with the total patient exposure now at approximately 218,500 patient years.

About Novartis in Multiple Sclerosis
Novartis is committed to the research and development of new treatment options to offer the right treatment to the right patient at the right time, to meet patients’ needs at every stage of disease with innovative and targeted drugs.

In addition to its ongoing development program for Gilenya in pediatric MS and chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), the Novartis MS portfolio includes Extavia® (interferon beta-1b for subcutaneous injection). Investigational compounds include BAF312, currently in phase III clinical development and being investigated as an oral therapy for secondary progressive MS (SPMS). Novartis is also exploring the IL-17 pathway in MS.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “committed,” “ongoing,” “investigational,” “being investigated,” “exploring,” or similar terms, or by express or implied discussions regarding potential future indications or labeling for Gilenya, potential future marketing submissions or approvals for the other investigational compounds in the
Novartis MS portfolio, or regarding potential future revenues from any or all of the products and investigational compounds in the Novartis MS portfolio, including Gilenya. 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 Gilenya will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that any of the investigational compounds in the Novartis MS portfolio will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that any of the products and investigational compounds in the Novartis MS portfolio will be commercially successful in the future. In particular, management’s expectations regarding these products 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 manufacturing 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 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). As of December 31, 2014 Novartis Group companies employed approximately 133,000 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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