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Gilenya® data at AAN to highlight Novartis leadership in innovation with new MS assessment methods to benefit patients and physicians

- New analysis will confirm high efficacy of Gilenya® in achieving 'no evidence of disease activity' (NEDA4) in previously-treated highly-active RMS patients
- Separate analyses will show adding brain shrinkage to an existing assessment tool enhances ability to predict disability progression in relapsing MS (RMS)
- Early data on a novel method to assess motor function in patients with MS and its potential clinical application will also be presented at AAN

Basel, 13 April 2015 – Novartis announced today new Gilenya® analyses to be presented at the 67th American Academy of Neurology (AAN) Annual Meeting in Washington, DC, USA from April 18-25, 2015, showing how Novartis is advancing methods assessing the impact of relapsing multiple sclerosis (RMS) for patients and physicians. Data will show how adding brain shrinkage (brain volume loss) to an existing tool to assess MS disease activity (m-Rio) will give a more precise prediction of the likelihood of future disability progression. Accurate assessment of disease activity is key to guide treatment decisions in RMS.

A pooled analysis from the two-year phase III FREEDOMS and FREEDOMS II trials will further confirm Gilenya’s high efficacy in previously-treated patients with highly-active RMS in achieving ‘no evidence of disease activity’ (NEDA4) across four key measures: relapses, MRI lesions, brain shrinkage and disability progression. Achieving NEDA4 is especially critical for highly-active RMS patients, who are likely to lose more physical and cognitive functions over time despite being treated.

“Novarits is committed to innovation beyond the research and development of new treatments, to help physicians and patients improve how multiple sclerosis is managed,” said Vasant Narasimhan, Global Head of Development at Novartis Pharmaceuticals. “These Gilenya data and new methods of assessing the impact of MS have the potential to give physicians a more comprehensive picture of an individual’s disease and allow patients to better understand their MS.”

Additional data will also be presented on ASSESS-MS, a project in early development which uses an innovative movement recording system and aims to quantify an individual’s level of disability in a non-invasive, patient-friendly manner. It measures a patient’s movements using the Microsoft Kinect® sensor with machine learning algorithms. Developed in collaboration with leading MS experts and Microsoft Research, ASSESS-MS may have the potential to change how neurological dysfunction and disability progression are assessed in MS patients.

Novartis MS portfolio highlights at AAN will include three poster presentations on ASSESS-MS; 16 presentations on Gilenya trial analyses; and one poster presentation on BAF312, an S1P-modulator that is being investigated for secondary progressive MS (SPMS).
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 the 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 relapsing MS 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 114,000 patients, with the total patient exposure now at approximately 195,000 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 polyneuropathy (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 “to highlight,” “will,” “to be presented,” “committed,” “potential,” “being investigated,” “ongoing,” “investigational,” “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, cost-saving generic pharmaceuticals, preventive vaccines and over-the-counter products. 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). Novartis Group companies employ approximately 130,000 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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* Kinect® is a registered trademark of Microsoft Corporation.

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