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Brain shrinkage is associated with a loss of physical and cognitive function and occurs at a faster rate in people with MS than those without the disease

New data showed patients who had the highest rates of brain shrinkage (brain volume loss) at two years had a higher risk of disability progression at four years

Separate analyses showed that patients continuously treated with Gilenya for six years had sustained low rates of brain shrinkage

Basel, Sept 10, 2014 – Novartis announced today that new data presented at the Joint ACTRIMS-ECTRIMS Meeting in Boston, USA, reinforces the clinical importance of measuring brain shrinkage (brain volume loss) in multiple sclerosis (MS). An association between the rate of brain shrinkage and increased risk of long-term disability progression was confirmed in patients with MS [1]. In pooled data from the phase III FREEDOMS core and extension studies, patients were categorized into four groups (quartiles) based on the mean change in brain volume from the start of the study to year-two. The analysis showed that 24.2% of patients who had the highest rate of brain shrinkage at 2 years had confirmed six-month disability progression at four years, compared to 15.4% of patients with the lowest rate of brain shrinkage (p=0.018) [1].

A separate analysis from the long-term follow-up extension study LONGTERMS, showed that the rate of brain shrinkage in patients treated with Gilenya® (fingolimod) remained similar throughout the six-year period, between 0.33% and 0.46% [2]. This was broadly in the range you would expect to see in people without MS, while the typical rate of brain shrinkage experienced by patients with MS is approximately 0.5% to 1.35% per year [3-6].

“Novartis is committed to generating data that advances science and clinical practice to improve the outcomes of patients. These new findings strengthen the link between brain shrinkage and long-term disability progression, supporting the significance of brain shrinkage for people with MS,” said Vasant Narasimhan, Global Head of Development at Novartis Pharmaceuticals. “The new data showing sustained low rates of brain shrinkage in Gilenya-treated patients with MS are reassuring because of the chronic debilitating nature of the disease.”

The rate of brain shrinkage for people with MS is around three to five times faster than people without the disease[3-6], and what is lost cannot be recovered. Brain shrinkage can start early[7-10], often goes unnoticed and is associated with a loss of physical and cognitive (i.e. memory) function for patients with MS
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Analyses of the pooled data from the phase III FREEDOMS core and extension studies showed that irrespective of treatment received brain shrinkage was associated with future long-term disability progression[2].

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[12]. The evolution of MS results in an increasing loss of both physical (e.g. walking) and cognitive (e.g. memory) function [13]. This has a substantial negative impact on the approximately 2.3 million people worldwide affected by MS
[14]
, a disease that begins in early adulthood, most often between the ages of 20 and 40
[15]
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The loss of physical and cognitive function in MS 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[16-18].

About Gilenya

Gilenya is the only oral disease-modifying therapy (DMT) to impact the course of relapsing-remitting MS (RRMS) with high efficacy across four key measures of disease activity: relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression[19-23].

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’)[24-26]. It is important to address both focal and diffuse damage in RRMS to effectively impact disease activity and help preserve an individual’s physical (e.g. walking) and cognitive (e.g. memory) function.

Gilenya has been used to treat more than 100,000 patients in a clinical trial and post-marketing setting over ten years and has a well-established safety profile.

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 primary progressive MS (PPMS), pediatric MS and chronic inflammatory demyelinating polyneuropathy (CIDP), the Novartis MS portfolio includes Extavia® (interferon beta-1b for subcutaneous injection). Investigational compounds include BAF312 (siponimod), currently in Phase III clinical development and being developed as the first 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,” “can,” “ongoing,” “investigational,” “being developed,” “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, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 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 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com .

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