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Gilenya® data at ACTRIMS-ECTRIMS to show Novartis is redefining MS treatment goals for patients

- ‘No evidence of disease activity’ (NEDA), the ultimate treatment goal in MS, is currently assessed by measuring relapses, MRI lesions and disability progression
- New Gilenya data will highlight importance of brain shrinkage as NEDA fourth key measure, giving physicians more complete assessment of MS disease in patients
- Separate analyses will confirm the clinical relevance of brain shrinkage based on its association with future long-term MS disability progression

Basel, Sept 3, 2014 – Novartis announced today that new analyses to be presented at the Joint ACTRIMS-ECTRIMS Meeting in Boston, USA from September 10-13, 2014, will add to the growing evidence confirming the importance of redefining treatment goals in multiple sclerosis (MS). The goal of MS treatment is to have ‘no evidence of disease activity’ or ‘NEDA’, which is currently defined as no evidence of relapses, MRI lesions and disability progression. New data to be presented will reinforce the clinical relevance of brain shrinkage (brain volume loss) and highlight the benefit of including it as a fourth key measure of MS in the definition of NEDA. In addition, other analyses will show that patients treated with Gilenya® (fingolimod) were more likely to achieve NEDA based on assessment of these four key measures, including MS-related brain shrinkage, than those on placebo.

Everyone’s brain shrinks as they age, but people with MS experience brain shrinkage up to three to five times faster. Brain shrinkage begins early in MS, even before symptoms occur, and is associated with a loss of physical and cognitive function.

New Gilenya analyses will show how brain shrinkage is associated with future long-term disability progression in patients with MS and that patients with relapsing MS treated with Gilenya had lower rates of brain shrinkage that importantly were sustained over time. The findings will also provide further evidence of the high efficacy of Gilenya on MS disease activity across four key measures.

“The data at ACTRIMS-ECTRIMS will reinforce the role of brain shrinkage and its association with future long-term MS disability progression,” said Vasant Narasimhan, Global Head of Development at Novartis Pharmaceuticals. “Novartis is committed to improving treatment outcomes for people with MS, and we believe that by including brain shrinkage as part of NEDA, clinicians can gain a more complete understanding of disease progression and treatment effects.”

Novartis MS portfolio highlights at the Joint ACTRIMS-ECTRIMS Meeting will include four oral presentations and 22 poster presentations on Gilenya, and two poster presentations on siponimod.
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 (e.g. walking) 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 begins in early adulthood, most often between the ages of 20 and 40.

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.

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.

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 RRMS to effectively impact disease activity and help preserve an individual’s physical (e.g. walking) and cognitive (e.g. memory) function.

To date, more than 100,000 patients worldwide have been treated with Gilenya in both clinical trial and post-marketing setting.

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 “to show,” “goal,” “will,” “to be presented,” “committed,” “believe,” “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 healthcare 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References


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