Media Release | Medienmitteilung | Communiqué Aux Médias

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# Sandoz announces US launch of Glatopa™, the first generic competitor to Copaxone® 20mg

- *Glatopa is the first FDA-approved, substitutable generic version of Copaxone® 20mg, a treatment for relapsing forms of multiple sclerosis*
- *Sandoz has begun shipping to US customers following recent FDA approval*
- *Novartis and Sandoz are driving access to a full range of differentiated, high-quality MS therapeutic options, complemented by a full range of support services*

**Holzkirchen, Germany, June 18, 2015** – Sandoz, a Novartis company, today announced the US launch of Glatopa™, the first generic version of Teva's Copaxone® (glatiramer acetate injection) 20 mg/ml one-time-daily multiple sclerosis therapy.

"Sandoz, together with Momenta, is proud to announce the US market launch of a fully substitutable generic version of this important therapy, following FDA approval" said Peter Goldschmidt, President of Sandoz US.

MS is a debilitating disease affecting about half a million individuals in the US alone; only half of those diagnosed are currently treated.[1]

Glatopa, developed in collaboration with Momenta and produced entirely in the US, is indicated for the treatment of patients with relapsing forms of MS, including those who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS.

The Sandoz service offering will include financial assistance to qualified patients, personalized injection training and 24-hour access to nurses for non-clinical questions.

Fighting MS, together with other CNS disorders, is central to the Novartis mission, and Sandoz's Glatopa joins a broad MS portfolio including two approved therapies and one late-stage development compound.

**Important Safety Information**
Glatiramer acetate is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol.

Approximately 16% of glatiramer acetate patients vs. 4% of those on placebo experienced a constellation of symptoms immediately after injection that included at least 2 of the following: flushing, chest pain, palpitations, anxiety, dyspnea, throat constriction, and urticaria. These symptoms generally have their onset several months after the initiation of treatment, although they may occur earlier, and a given patient may experience 1 or several episodes of these symptoms. Typically, the symptoms were transient and self-limited and did not require

[1] National Multiple Sclerosis Society: "MS Prevalence -- National Multiple Sclerosis Society." Accessed on March 12, 2014 from http://www.nationalmssociety.org/About-the-Society/MS-Prevalence

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treatment; however, there have been reports of patients with similar symptoms who received emergency medical care.

Transient chest pain was noted in 13% of glatiramer acetate patients vs. 6% of placebo patients. While some episodes of chest pain occurred in the context of the immediate post-injection reaction described above, many did not. The temporal relationship of this chest pain to an injection was not always known. The pain was transient, often unassociated with other symptoms, and appeared to have no clinical sequelae. Some patients experienced more than 1 such episode, and episodes usually began at least 1 month after the initiation of treatment.

At injection sites, localized lipoatrophy and, rarely, injection site skin necrosis may occur. Lipoatrophy may occur at various times after treatment onset (sometimes after several months) and is thought to be permanent. There is no known therapy for lipoatrophy.

Because glatiramer acetate can modify immune response, it may interfere with immune functions. For example, treatment with glatiramer acetate may interfere with recognition of foreign antigens in a way that would undermine the body's tumor surveillance and its defenses against infection. There is no evidence that glatiramer acetate does this, but there has not been a systematic evaluation of this risk.

The most common adverse reactions with glatiramer acetate vs placebo were injection site reactions (ISRs), such as erythema (43% vs 10%); vasodilatation (20% vs 5%); rash (19% vs 11%); dyspnea (14% vs 4%); and chest pain (13% vs 6%). ISRs were one of the most common adverse reactions leading to discontinuation of glatiramer acetate. ISRs, such as erythema, pain, pruritus, mass, edema, hypersensitivity, fibrosis, and atrophy, occurred at a higher rate with glatiramer acetate than placebo.
To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for glatiramer acetate.

**Disclaimer**
This press release contains forward-looking statements that can be identified by words such as "driving," "commitment," "offer," "mission," or similar terms, or by express or implied discussions regarding potential future marketing submissions or approvals for the development compounds in the Novartis MS portfolio, or regarding potential future revenues from any or all of the products and development compounds in the Novartis MS portfolio, including Glatopa, or any other Sandoz products. 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 any of the development compounds in the Novartis MS portfolio will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that any of the products and development compounds in the Novartis MS portfolio, including Glatopa, or any other Sandoz products, will be commercially successful in the future. In particular, management's expectations regarding these products could be affected by, among other things, unexpected

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regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues; unexpected patent litigation outcomes; the company's ability to obtain or maintain proprietary intellectual property protection, 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 Sandoz**

Sandoz, a division of Novartis, is a global leader in generic pharmaceuticals, driving sustainable access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe.

The Sandoz global portfolio comprises approximately 1,100 molecules, which accounted for 2014 sales of USD 9.6 billion. Sandoz holds the global #1 position in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines. In addition, Sandoz holds leading global positions in key therapeutic areas ranging from generic injectables, dermatology and respiratory to cardiovascular, metabolism, central nervous system, pain and gastrointestinal.

Sandoz develops, produces and markets finished dosage form (FDF) medicines as well as intermediary products including active pharmaceutical ingredients (APIs) and biotechnological substances. Nearly half of Sandoz's portfolio is in differentiated products – products that are scientifically more difficult to develop and manufacture than standard generics.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has consistently driven growth in selected geographies and differentiated product areas through a series of targeted acquisitions, including Hexal (Germany), EBEWE Pharma (Austria), and Fougera Pharmaceuticals (US).

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global.

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