Sandoz International
Sandoz Global Communications
Industriestr. 25
83607 Holzkirchen
Germany

www.sandoz.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Sandoz announces US FDA approval and launch of Glatopa® 40 mg/mL three times-a-week generic option for relapsing forms of multiple sclerosis

- *Glatopa® 40 mg/mL is a fully substitutable, AP-rated generic version of Copaxone®* (glatiramer acetate injection) 40 mg/mL*
- *Glatopa 40 mg/mL, along with Glatopa® 20 mg/mL, which was launched in the US in June 2015, will offer patients a complete range of dosing options*
- *A full range of patient support services for Glatopa® is available through GlatopaCare®*

Holzkirchen, February 13, 2018 – Sandoz, a Novartis division, today announced the US FDA approval and launch of Glatopa® (glatiramer acetate injection) 40 mg/mL.

Glatopa (glatiramer acetate injection) 40 mg/mL is FDA-approved as a fully-substitutable, AP-rated generic version of Copaxone®* (glatiramer acetate injection) 40 mg/mL three times-a-week therapy for relapsing forms of multiple sclerosis (MS). Glatopa was developed under a collaboration agreement between Momenta Pharmaceuticals, Inc. and Sandoz and is produced in the US.

“The approval and launch of Glatopa 40 mg/mL reinforces our leadership in delivering complex, differentiated generic products. We look forward to bringing this product to patients and healthcare professionals and providing a full range of patient support services for Glatopa through GlatopaCare®,” said Richard Francis, CEO, Sandoz.

Glatopa 40 mg/mL is indicated for the treatment of patients with relapsing forms of multiple sclerosis. Glatopa 40 mg/mL, along with Glatopa 20 mg/mL, will offer patients a complete range of dosing options. Glatopa 20 mg/mL was made available in the US in June 2015. Patients can expect the same patient services for Glatopa 40 mg/mL as for Glatopa 20 mg/mL.

Sandoz GlatopaCare will offer a $0 co-pay support program to qualified patients. To help increase patient confidence with administering injections, patients will receive personalized injection training, 24-hour access to nurses for Glatopa®-related questions and a free Starter Kit, which includes the Glatopaject® injection device, designed to work with both Glatopa 20 mg/mL and 40 mg/mL prefilled syringes.

Glatopa® Indication and Important Safety Information

Indication

Glatopa® (glatiramer acetate injection) is indicated for the treatment of patients with relapsing-forms of multiple sclerosis.

Important Safety Information

Glatopa® is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol.

Approximately 16% of glatiramer acetate injection 20mg/mL patients vs. 4% of those on placebo, and approximately 2% of glatiramer acetate injection 40mg/mL patients vs. none on placebo experienced a constellation of symptoms that may occur within minutes after injection and included at least 2 of the following: flushing, chest pain, palpitations, tachycardia, 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 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 injection 20mg/mL patients vs. 6% of placebo patients, and approximately 2% of glatiramer acetate injection 40mg/mL patients vs. 1% on placebo. 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 injection 20mg/mL 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%). The most common adverse reactions with glatiramer acetate injection 40mg/mL vs placebo were ISRs, such as erythema (22% vs 2%).

ISRs were one of the most common adverse reactions leading to discontinuation of glatiramer acetate injection. 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 Glatopa.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential launches, marketing approvals, new indications or labeling for Glatopa 40 mg/mL, Glatopa 20 mg/mL and the other products

described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 Glatopa 40 mg/mL, Glatopa 20 mg/mL or the other products described in this press release will be launched, or submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such products will be approved for all indications included in the reference product's label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional competing versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and industry conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people's lives. We contribute to society's ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients and we aspire to reach one billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

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

Follow our blog at www.sandoz.com/makingaccesshappen.

*Copaxone is a registered trademark of Teva Pharmaceutical Industries Ltd.

# # #

Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Tim Willeford
Sandoz Global Communications
+49 80 24 4760 (mobile)
tim.willeford@sandoz.com

Chris Lewis
Sandoz Global Communications

Michelle Bauman
Sandoz Global Communications

+49 8924 476 1906 (direct)
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

+1 609 720 6699 (direct)
+1 973 714 8043 (mobile)
michelle.bauman@sandoz.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		