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Sandoz announces global deal to commercialize proposed biosimilar natalizumab, a key multiple sclerosis medicine

- *Worldwide agreement with Polpharma Biologics gives Sandoz commercialization rights to proposed biosimilar natalizumab for relapsing-remitting multiple sclerosis (RRMS)*
- *RRMS affects ~85% of MS patients and can create a substantial social and economic burden on patients, their families and healthcare systems^{1,2}*
- *Natalizumab is fifth proposed biosimilar in-licensed by Sandoz in nine months, underscoring commitment to further grow pipeline through collaborations*

Holzkirchen, Germany, September 3, 2019 – Sandoz, a Novartis division and a global leader in biosimilars, today announced that it has entered into a global commercialization agreement for a proposed natalizumab biosimilar. The medicine is in Phase III clinical development for the treatment of relapsing-remitting multiple sclerosis (RRMS).

Under the agreement, Polpharma Biologics will maintain responsibilities for development, manufacturing and supply of proposed biosimilar natalizumab. Sandoz will commercialize and distribute the medicine in all markets upon approval, through an exclusive global license. Other specific terms of the agreement are confidential. Polpharma Biologics is a European biopharmaceutical company with a fully integrated R&D and manufacturing footprint.

Reference medicine natalizumab is a disease-modifying therapy (DMT) that was approved for use over 10 years ago, offering patients a valuable therapeutic option for treating RRMS.

In addition to the personal burden of MS for patients and families, affordability is a significant challenge for MS medicines globally. A recent report highlighted affordability as the most common challenge affecting access to MS therapy in 46% of the 90 countries included¹. Elsewhere it has been highlighted that providing access to DMTs for MS represents a considerable challenge for healthcare systems³.

“Patient access to advanced medicines is important for all people diagnosed with a chronic disease, but the challenges are very pronounced for MS patients,” said Pierre Bourdage, ad interim Global Head of Biopharmaceuticals, Sandoz. “By nature, biosimilars create competition and cost savings, which are proven to make room in healthcare systems to treat more patients⁴. With this agreement, we hope to build on our MS experience with small molecules and complex generics, and ultimately provide patients with expanded access to a DMT that healthcare systems may otherwise not be able to provide.”

Sandoz continues to expand the biosimilars marketplace and is committed to help millions of patients access biologic medicines sustainably and affordably. The addition of proposed biosimilar natalizumab expands the Novartis/Sandoz portfolio across small molecules,

complex generics, biosimilars, and innovator medicines enabling broad patient access to patented and off-patent medicines. In addition to entering complex and underserved areas such as MS, Sandoz is already helping patients in the areas of immunology, oncology and endocrinology. The division has a leading global portfolio with eight marketed biosimilars and a further 10+ in development.

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 regulatory submissions, marketing approvals, launches, new indications or labeling for biosimilar natalizumab and the other products described in this press release, or regarding potential future revenues from biosimilar natalizumab and such other products, or regarding the proposed commercialization agreement with Polpharma Biologics. 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 biosimilar natalizumab or other Sandoz products will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that biosimilar natalizumab or other Sandoz products will be successfully launched, or at any particular time. Nor can there be any guarantee that, if approved, biosimilar natalizumab or such other Sandoz products will be approved for all indications in the originator product label. Neither can there be any guarantee that biosimilar natalizumab, such other Sandoz products, or the commercialization agreement with Polpharma Biologics will be commercially successful in the future. In particular, our expectations regarding the commercialization agreement with Polpharma Biologics and such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional biosimilar versions of natalizumab; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic 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, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars, and a pioneer in the emerging field of prescription digital therapeutics. Our purpose is to pioneer access to healthcare by developing and commercializing novel, affordable approaches that address unmet medical need. Our broad portfolio of high-quality medicines, covering all major therapeutic areas and increasingly focused on value-adding differentiated medicines, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

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

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5. McCamish M, Woollett G. The state of the art in the development of biosimilars. *Clin Pharmacol Ther* 2012;91(3):405–417 (Figure 7).

Novartis Media Relations

Central media line: +41 61 324 2200
Email: media.relations@novartis.com

Antonio Ligi
Novartis Global Media Relations
+ 41 61 324 1374 (direct)
+ 41 79 723 3681 (mobile)
Email: antonio.ligi@novartis.com

Chris Lewis
Sandoz Global Communications
+49 174 244 9501 (mobile)
Email: chris.lewis@sandoz.com

Michelle Bauman
Sandoz Global Communications
+1 973 714 8043 (mobile)
Email: michelle.bauman@sandoz.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

Email: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Sloan Simpson +1 862 778 3275
Cory Twining +1 212 830 2417