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Sandoz announces exclusive global collaboration with Biocon on next-generation biosimilars

- *Collaboration aims to help patients worldwide gain access to a range of high-quality, affordable immunology and oncology biologics*
- *Partnership will be an important part of Sandoz and Biocon strategy to address the next wave of biosimilar opportunities globally*
- *Collaboration will leverage combined strengths of development, manufacturing and commercialization of biosimilars*
- *Partnership provides foundation for expansion of portfolio*

Holzkirchen, 18 January 2018 – Sandoz, a Novartis division and the global leader in biosimilars, today announced a global partnership with Asia’s premier biopharmaceuticals company, Biocon, to develop, manufacture and commercialize multiple biosimilars in immunology and oncology for patients worldwide.

Under the terms of the agreement, both companies will share responsibility for end-to-end development, manufacturing and global regulatory approvals for a number of products, and will have a cost and profit share arrangement globally. Worldwide commercialization responsibilities will be divided and each company’s strengths will be leveraged within specific geographies. Sandoz will lead commercialization in North America* and the EU,** while Biocon will lead commercialization in Rest of the World.***

“Today’s announcement bolsters our leadership position in biosimilars and positions us to continue to lead well into the future,” said Richard Francis, CEO, Sandoz. “Biocon is a great complement to our proven biosimilar capabilities at Sandoz. Through this collaboration, we are reinforcing our long-term commitment to increase patient access to biologics.”

“Together, we will be able to realize benefits at every stage of the value chain, from development, through manufacturing to commercialization,” said Carol Lynch, Global Head, Biopharmaceuticals, Sandoz. “This collaboration further strengthens our ability to deliver next-generation biosimilar medicines to patients.”

Sandoz is committed to increasing patient access to high-quality biosimilars. We are the global leader in biosimilars, with five biosimilars currently marketed worldwide, as well as a leading global pipeline. Sandoz is well-positioned to continue leading the biosimilars industry based on our experience and capabilities in development, manufacturing and commercialization. As a division of Novartis, the first global healthcare company to establish a leading position in both innovative and off-patent medicines, we benefit strongly from this unique blend of experience and expertise in many different market environments.

As an innovation-led biopharmaceutical company, Biocon has successfully developed and taken a range of novel biologics, biosimilar antibodies, rh-insulin and insulin analogs from ‘lab to market’. The collaboration with Sandoz builds upon Biocon’s successful progress in its existing global biosimilars program. An early mover in the biosimilars space, Biocon has successfully launched its insulin glargine in Japan, trastuzumab and bevacizumab biosimilars in India and rh-insulin, insulin glargine and biosimilar trastuzumab in a few emerging markets; and it was the first Indian company to have a biosimilar approved by the US Food and Drug Administration.

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 “to develop,” “to commercialize,” “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” “expansion,” “portfolio,” “collaboration,” “partnership,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved biosimilar products described in this press release, or regarding potential future revenues from such products or the collaboration and partnership with Biocon. 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 the investigational or approved products described in this press release will be 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 biosimilar 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. Neither can there be any guarantee that the collaboration and partnership with Biocon will achieve any or all of its intended goals and objectives, or be commercially successful. In particular, our expectations regarding such products, and the collaboration and partnership with Biocon, 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 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 or Biocon from selling the products developed, manufactured and commercialized under the collaboration and partnership; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; potential or actual data security and data privacy issues; safety, quality or 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 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 2016 sales of USD 10.1 billion. In 2016, 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.

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**US and Canada*

*** including European Free Trade Association (EFTA) and Balkan states*

**** including Russia and Commonwealth of Independent States (CIS)*

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