Media Release Medienmitteilung Communiqué Aux Médias

Sandoz International
Industriestr. 25
83607 Holzkirchen,Germany
Tel: +49 8024 476 2596
Fax: +49 8024 476 2599
www.sandoz.com

Sandoz enters into commercialization and supply agreement for insulin biosimilars, anticipating growing demand as diabetes burden rises

- *Agreement covers biosimilar insulins in early and clinical development for the top three selling branded insulins by sales: glargine, lispro and aspart*
- *Over 400 million people worldwide have diabetes and the amount of insulin required to treat type 2 diabetes alone is expected to increase by more than 20% from 2018 to 2030*[1,2]
- *Sandoz continues to strategically expand their biosimilars portfolio, with eight marketed biosimilars and a robust pipeline, showing ongoing commitment to accessible innovation*

Holzkirchen, Germany, December 19, 2018 – Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announced that it has entered into an agreement to commercialize biosimilar versions of insulins used in patients with type 1 and type 2 diabetes. These medicines are currently in early and clinical stages of development for the European Union (EU), United States (US) and other key territories.

The commercialization and supply agreement with Gan & Lee aims at bringing to market biosimilar versions of glargine, lispro and aspart, the three top insulin medicines by sales. Gan & Lee is a leading insulin supplier headquartered in China with more than 20 years' experience in insulins and production capacity with attractive cost of goods sold (COGS) structures. Under the terms of the agreement, Sandoz will be fully responsible for commercializing these medicines in the EU, US, Switzerland, Japan, South Korea, Canada, Australia and New Zealand. Gan & Lee will be responsible for manufacturing and development, with support from Sandoz, and shall adhere to the stringent manufacturing requirements established for Sandoz biosimilars. Other specific terms of the agreement are confidential.

In 2015, total global health expenditure due to diabetes was estimated at 673 billion US dollars, roughly 12% of overall global health expenditure[3]. The concerns on insulin affordability have been increasingly noted with the US Food and Drug Administration stating in December 2018 that "access to affordable insulin is literally a matter of life and death for (certain) Americans[4]."

Sandoz has significant experience disrupting and transforming the healthcare landscape with off-patent medicines including generics, biosimilars and most recently digital therapeutics. This agreement enables Sandoz to expand the existing endocrinology portfolio over the long-term, in-line with its strategy to expand its biosimilar business, and enter the insulins business at attractive investment terms. It also builds on the scientific and commercial expertise of Sandoz, including the approval and launch of eight biosimilar medicines, while leveraging the collaborator's experience in developing quality insulin medicines and high-volume manufacturing.

When the pancreas does not produce enough insulin, a hormone that regulates blood sugar, a serious chronic disease called diabetes can occur. It is estimated that more than 400 million adults worldwide are living with diabetes, and that number is expected to rise. People with diabetes may develop blindness, kidney failure, and cardiovascular disease[1,5].

"Across the world, people suffering from diabetes still face very real access challenges. In fact, US patients have reported taking less insulin than recommended by their doctor because they couldn't afford it – putting them at higher risk for serious complications[6]," said Richard Francis, CEO, Sandoz. "At Sandoz, we have significant experience disrupting and transforming marketplaces, and look forward to extending access for the more than 420 million people worldwide suffering from diabetes."

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“Tackling the personal and healthcare burden of diabetes has become a global priority. With a majority of insulin therapy offered by just a few companies, healthcare systems and the insulin supply are under increasing pressure to meet the growing demands[1,2],” said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz. “As the pioneer and global leader in biosimilars, Sandoz is proud to expand our endocrinology portfolio into insulins to help people living with diabetes access the medicines they need for the long-term.”

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 “anticipating,” “growing,” “expected,” “continues,” “strategically,” “portfolio,” “pipeline,” “commitment,” “will,” “strategy,” “builds on,” “look forward,” “launch,” “increasing,” or similar terms, or by express or implied discussions regarding potential regulatory submissions, marketing approvals or launches for the investigational biosimilar products described in this press release, or regarding potential future revenues from such products or the commercialization and supply agreement with Gan & Lee. 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. You should not place undue reliance on these statements. There can be no guarantee that the investigational biosimilar products described in this press release will be submitted or approved for sale or successfully launched 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 biosimilar products will be commercially successful in the future. Neither can there be any guarantee that the commercialization and supply agreement with Gan & Lee will achieve any or all of its intended goals and objectives, or be commercially successful. In particular, our expectations regarding such products and the commercialization and supply agreement with Gan & Lee 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 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 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 1,000 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. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

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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

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

Michelle Bauman
Sandoz Global Communications
+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		