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MEDIA & INVESTOR RELEASE

Sandoz announces exclusive deal to commercialize biosimilar ustekinumab, further reinforcing growing pipeline and immunology patient offering

- *Agreement with Samsung Bioepis gives Sandoz exclusive commercialization rights to biosimilar SB17 ustekinumab in Europe and North America*

- *Ustekinumab is a fully human monoclonal antibody to interleukin (IL)-12/23, approved for treatment of plaque psoriasis, psoriatic arthritis, Crohn´s disease and ulcerative colitis*

- *Deal further strengthens Sandoz position in immunology and supports further pipeline expansion*

Basel, September 11, 2023 — Sandoz, a global leader in generic and biosimilar medicines, today announced that it has entered into a development and commercialization agreement with Samsung Bioepis.

The agreement provides Sandoz with the exclusive rights to commercialize the biosimilar SB17 ustekinumab in the US, Canada, EEA, Switzerland, and UK. Other specific terms of the agreement are confidential.

“This deal represents another major step to reinforce our high-value biosimilar pipeline, in line with our plans to become a standalone global leader,” says Sandoz CEO Richard Saynor. “It will further strengthen our immunology patient offering and means we now have five potential high-value upcoming biosimilar launches over the next few years.”

The reference medicine Stelara (ustekinumab) is a monoclonal antibody medication to interleukin (IL)-12/23 for the treatment of autoimmune disorders including Crohn's disease, plaque psoriasis, psoriatic arthritis, and ulcerative colitis.

Psoriasis is a chronic inflammatory disease of the skin and other parts of the body, which affects 60 million people worldwide[1]. Psoriasis has a huge impact on patients´ quality of life (QoL) and has a substantial economic burden, with annual mean costs of up to EUR 11,928 per patient globally[2].

Inflammatory bowel diseases (Crohn´s disease and ulcerative colitis) are chronic gastrointestinal disorders that affect more than 3 million people in Europe and in the US[3], with a high associated economic burden and annual direct costs of up to 6 bn in Europe[4] and 25.4 bn USD[5] in the USA. IBD negatively impacts patients’ quality of life by affecting daily activities, work ability and social life[6].

The clinical development program for SB17, a ustekinumab biosimilar, is well advanced and Phase I results were presented at the American Academy of Dermatology (AAD) Annual Meeting held in New Orleans, US, in March 2023 by Samsung Bioepis. This study demonstrated that SB17 matches reference ustekinumab in terms of pharmacokinetic (PK) bioequivalence, safety, tolerability, and immunogenicity.· SB17 Phase III clinical study results will be presented at a medical congress later this year.

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,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved 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 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 generic or 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. In particular, our expectations regarding 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 generic or biosimilar versions of such products; 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, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity 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.

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About Sandoz
Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our vision is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines covers major therapeutic areas.

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