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MEDIA & INVESTOR RELEASE

Sandoz Biologics License Application for proposed biosimilar denosumab accepted by US FDA

- *Submission supported by comprehensive analytical and clinical data package*
- *Denosumab indicated for treating variety of conditions including osteoporosis in postmenopausal women*[1,2]
- *Sandoz continues to build biosimilars portfolio to increase patient access to high-quality therapies and support healthcare system sustainability*

Basel, February 06, 2023 — Sandoz, a global leader in off-patent (generic and biosimilar) medicines, today announced that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) for proposed biosimilar denosumab.

The application includes all indications covered by the reference medicines Prolia® (denosumab)* and Xgeva® (denosumab)* for treating a variety of conditions, including osteoporosis in postmenopausal women and in men at increased risk of fractures, treatment-induced bone loss, prevention of skeletal related complications in cancer that has spread to the bone, giant cell tumor of the bone, and treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.[1,2]

“In addition to being an important medicine for cancer of the bone, denosumab is critical in the treatment of osteoporosis and potential prevention of osteoporosis-related fractures that so many women over 50 are at risk of,” said Keren Haruvi, President, Sandoz Inc. and Head of North America.

“We are proud to be among the first to submit a BLA for a denosumab biosimilar as, if approved, it could increase patient access to an affordable, high-quality, potentially disease-modifying treatment across the US, while also delivering savings for healthcare systems.”

In the US alone, more than 10 million adults over age 50 are estimated to have osteoporosis, of whom more than 80% are women.[3] It is predicted that one in two of these women and one in four men will have an osteoporosis-related fracture in their lifetimes.[4] Osteoporosis-related fractures may lead to diminished quality of life, disability, and even death.[5]

The BLA includes a comprehensive analytical and clinical data package, including data from the Phase I/III ROSALIA study. Results confirmed that the proposed biosimilar denosumab matches the reference medicine in terms of pharmacokinetics, pharmacodynamics, efficacy, safety and immunogenicity in women with postmenopausal osteoporosis; and contributes to demonstration of similarity, which is the basis for use in all indications.

Sandoz biosimilars help patients, in areas including immunology, oncology, supportive care and endocrinology, access critical and potentially life-changing medicines sustainably and

affordably. Sandoz has a leading global portfolio with eight marketed biosimilars and a further 15-plus in various stages of development.

About denosumab

Denosumab is a human monoclonal antibody designed to bind to the RANKL protein, an activator of osteoclasts (cells involved in breaking down bone tissue).[1] By binding to and inhibiting RANKL, denosumab decreases the production and activity of osteoclasts, resulting in a reduction of bone loss, and subsequently the likelihood of fractures and other serious bone conditions.[6]

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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*Prolia® and Xgeva® are registered trademarks of Amgen Inc.

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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 ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering major therapeutic areas, accounted for 2022 sales of USD 9.2 billion.

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