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MEDIA & INVESTOR RELEASE

Sandoz announces further progress on its biosimilar pipeline, with release of positive results for denosumab integrated Phase I/III clinical trial

- *ROSALIA study met primary endpoints, confirming proposed biosimilar denosumab matches reference product in terms of pharmacokinetics, pharmacodynamics, efficacy, safety and immunogenicity in postmenopausal women with osteoporosis*
- *Osteoporosis accounts for 8.9 million bone fractures annually, including debilitating hip fractures – a number set to increase substantially over next two decades*[1]
- *Positive trial results follow filing acceptances for two other proposed Sandoz biosimilars, adalimumab HCF and natalizumab, by both EMA and FDA*

Basel, September 19, 2022 – Sandoz, a global leader in off-patent (generic and biosimilar) medicines, today announces further progress on its biosimilar pipeline, with the release of positive results from the integrated ROSALIA Phase I/III clinical trial study for its proposed biosimilar denosumab.

"Biosimilars have the opportunity to create a substantial positive impact on patient access and healthcare systems sustainability," said Florian Bieber, Global Head of Development, Sandoz Biopharmaceuticals. "Therefore, this important milestone means that we are one step closer to giving individuals living with osteoporosis access to a more affordable, biosimilar version of this critical medicine, which may help to change the course of their disease."

Denosumab is indicated for treating a variety of conditions, including osteoporosis in postmenopausal women, in men at increased risk of fractures, treatment-induced bone loss, prevention of skeletal related complications in cancer that has spread to the bone, and giant cell tumor of the bone[2,3,4,5].

The results from the integrated Phase I/III study confirm the biosimilar matches the reference medicine in terms of pharmacokinetics, pharmacodynamics, efficacy, safety and immunogenicity in the respective indications; and contributes to demonstration of similarity, which is the basis for use in all indications.

Approximately 500 million men and women worldwide may be affected by osteoporosis[1], which causes 8.9 million fractures annually – or one fracture every three seconds[1]. By 2050, hip fractures are projected to increase by 240% in women and 310% in men compared to 1990[1].

The results come soon after Sandoz confirmed acceptance of license applications for two other proposed biosimilars. In July 2022, the application for the first-of-a-kind multiple sclerosis proposed biosimilar natalizumab was accepted for review by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). In June 2022, the EMA and

FDA accepted for review Sandoz applications for the high-concentration formulation 100 mg/mL (HCF) of its biosimilar adalimumab.

Sandoz biosimilars help patients, in areas including immunology, oncology, nephrology, 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 ROSALIA[6]
In ROSALIA, 527 postmenopausal women with osteoporosis were randomized to receive either biosimilar denosumab or the reference medicine for up to 78 weeks of treatment. Objectives were to demonstrate similar efficacy in terms of change in lumbar spine bone mineral density, as well as similar pharmacokinetics and pharmacodynamics. The global clinical program for biosimilar denosumab was developed in consultation with major regulatory agencies and the results from this clinical study are expected to support regulatory approval.

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)[2]. 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[2].

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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.

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 all major therapeutic areas, accounted for 2021 sales of USD 9.6 billion.

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