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MEDIA & INVESTOR RELEASE

Sandoz Marketing Authorization Applications for proposed biosimilar denosumab accepted by EMA

- *Submissions supported by comprehensive analytical and clinical data package including a Phase I PK/PD similarity study and the integrated Phase I/III ROSALIA clinical trial*

- *Denosumab is indicated for treating a variety of conditions, including osteoporosis in postmenopausal women, prevention of skeletal related complications in cancer that has spread to the bone and unresectable giant cell tumor of the bone*[1,2]

- *Sandoz continues to build its biosimilars portfolio to increase patient access to high-quality, affordable biologics and generate savings for health systems*

Basel, May 25, 2023 — Sandoz, a global leader in off-patent (generic and biosimilar) medicines, today announced that the European Medicines Agency (EMA) has accepted the marketing authorization applications (MAA) for proposed biosimilar denosumab for regulatory review.

The two applications include all indications covered by the reference medicines Prolia® (denosumab)* and Xgeva® (denosumab)*, respectively, 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 have spread to the bone, and giant cell tumor of the bone.[1,2]

“Sandoz is one of the first to have its applications for a proposed biosimilar denosumab accepted by the EMA. If approved, this has the potential to provide people living with osteoporosis and cancer of the bone or bone metastasis access to a cost-effective and high-quality treatment option.” said Florian Bieber, Development Platform Head Biopharmaceuticals and Chief Medical Officer, Sandoz. “This news follows the recent application acceptance by the US Food and Drug Administration and supports our continued commitment to providing expanded access to life-changing treatments, while also helping over-burdened healthcare systems generate savings.”

Approximately 500 million men and women worldwide may be affected by osteoporosis, which causes 8.9 million fractures annually – or one fracture every three seconds.[3] By 2050, hip fractures are projected to increase by 240% in women and 310% in men compared to 1990.[3] Prevalence of skeletal related complications in cancer is estimated to be as high as 63% for breast cancer, 59% for lung cancer and 52% for prostate cancer. Skeletal related complications in cancer are associated with loss of mobility and social functioning, reduced quality of life, increased health care expenditure and worse survival.[4,5,6]

The EMA applications are based on a comprehensive analytical and clinical data package, comprised of data from a Phase I PK/PD similarity study in healthy volunteers and the integrated Phase I/III ROSALIA study. The data package confirmed the denosumab biosimilar matches the reference medicine in terms of pharmacokinetics, pharmacodynamics, efficacy, safety, and immunogenicity in the respective study populations; and contributes to the demonstration of similarity, which is the basis for use in all indications for which Xgeva and Prolia are approved.

Sandoz is committed to helping millions of patients sustainably and affordably access critical and potentially life-changing biologic medicines across a range of areas including immunology, oncology, supportive care and endocrinology. It has a leading global portfolio with eight marketed biosimilars and a further 24 assets in various stages of development. Since launching the first biosimilar in Europe in 2006, Sandoz has proven biosimilars create early and expanded patient access to life-altering medicines while increasing healthcare savings and creating competition that fuels innovation and development of new and enhanced treatments in areas of unmet need.

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.[7]

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looking statements contained in this press release as a result of new information, future events or otherwise.

References

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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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