SANDOZ

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MEDIA RELEASE

Sandoz receives European Commission approval for Wyost® and Jubbonti®, the first and only biosimilars of denosumab in Europe

- Wyost® (denosumab) and Jubbonti® (denosumab) approved by EC for all indications of denosumab reference medicines Xgeva® and Prolia®
- EC approval based on robust development program confirming that biosimilar matches reference medicine in terms of safety, efficacy and quality
- Approved for treatment of cancer-related bone disease and osteoporosis respectively

Basel, May 22, 2024 – Sandoz, the global leader in generic and biosimilar medicines, today announced that the European Commission (EC) has granted marketing authorization for Wyost®[1] (denosumab) and Jubbonti®[2] (denosumab), the first and only biosimilar versions of reference medicines Xgeva®*[3] and Prolia®*[4] in Europe.

Wyost® is approved for the treatment of cancer-related bone disease.[1] Jubbonti® is approved to treat osteoporosis.[2] These are key biosimilar value drivers for the company over the mid-term and their approval is a major step in advancing the Sandoz growth strategy. We expect to launch from November 2025 onwards.

"Primary and secondary bone loss, as well as cancer-related bone events, represent an immense disease burden for patients, the economy and society as a whole. The approval of the first European denosumab biosimilars is a crucial recognition of the need for increased access to these potentially life-changing medicines and demonstrates our continued commitment to delivering more sustainable treatment options for patients, in Europe and beyond."

Claire D'Abreu-Hayling, Chief Scientific Officer

Close to one quarter (4.2 million) of all newly reported cancer cases globally occur in Europe and cancer is ranked as a leading cause of premature death among those 30–69 years of age in most European countries.[5] Nearly all types of

cancer can spread to the bone and cause pain and fractures, though cancers that often metastasize in bones include breast and prostate.[6]

In Europe, 32 million people over 50 years were estimated to live with osteoporosis in 2019 with the number of fractures per year set to increase by almost 25% until 2034.[7] Despite wide availability of treatments only a minority of patients at high risk currently receive treatment, even after their first fracture.[8]

About Wyost® and Jubbonti®

Wyost® and Jubbonti® have been developed to match the reference medicines. Both medicines contain the same active ingredient (denosumab), a human monoclonal antibody (IgG2) that targets and binds with high affinity and specificity to RANKL, preventing activation of its receptor, RANK, on the surface of osteoclast precursors and osteoclasts. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone.

The EC approvals are based on robust development programs. Wyost and Jubbonti have the same dosage form, route of administration, dosing regimen and presentation as the respective reference medicines.

Wyost is indicated in Europe to prevent skeletal related events (SREs; pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone and to treat adults and skeletally mature adolescents with a giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity[1].

Jubbonti is indicated in Europe to treat osteoporosis in postmenopausal women and in men at increased risk of fractures, of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures, and bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture[2].

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

Disclaimer

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

References

1. European Medicines Agency (EMA). Wyost® (Denosumab): Prescribing Information. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/wyost [Last accessed: May 2024]

2. European Medicines Agency (EMA). Jubbonti ® (Denosumab): Prescribing Information. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/jubbonti [Last accessed: May 2024]
3. European Medicines Agency (EMA). Xgeva® (Denosumab): Prescribing Information. Available from: https://www.ema.europa.eu/en/documents/overview/xgeva-epar-medicine-overview_en.pdf [Last accessed: May 2024].
4. European Medicines Agency (EMA). Prolia® (Denosumab): Prescribing Information. Available from: https://www.ema.europa.eu/en/documents/overview/prolia-epar-summary-public_en.pdf [Last accessed: May 2024].
5. The Cancer Atlas. The Burden of Cancer. Available from: https://canceratlas.cancer.org/the-burden/the-burden-of-cancer/ [Last accessed: May 2024]
6. American Cancer Society. Bone Metastases. Available from: https://www.cancer.org/treatment/understanding-your-diagnosis/advanced-cancer/bone-metastases.html [Last accessed: March 2024]
7. International Osteoporosis Foundation. SCOPE '21. ScoreCard for OsteoPorosis in Europe. Available from: https://www.osteoporosis.foundation/sites/iofbonehealth/files/2022-01/Slide%20set%20-%20EU%20general.pdf [Last accessed: May 2024]
8. International Osteoporosis Foundation. Facts and Statistics. Available from: https://www.osteoporosis.foundation/facts-statistics/epidemiology-of-osteoporosis-and-fragility-fractures [Last accessed: May 2024]

About Sandoz

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of more than 100 nationalities work together to ensure 800 million patient treatments are provided annually by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,500 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the first biosimilar in 2006.

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