Press Release

EMA accepts Marketing Authorization Applications for AVT03, a Proposed Denosumab Biosimilar

- STADA announces EMA acceptance of Marketing Authorization Applications for AVT03, a proposed denosumab biosimilar to Prolia® (Bone Health) and Xgeva® (Oncology)
- STADA holds marketing rights for AVT03 in Europe, as well in selected markets in Central Asia and the Middle East
- STADA's Global Specialty Head, Bryan Kim: "Approval for a denosumab biosimilars would complement the expertise and experience we have gained through our market-leadership in Europe's teriparatide osteoporosis treatments market. We also look forward to expanding our offering to the oncology community, which we already serve through a broad portfolio that includes a bevacizumab biosimilar."

Bad Vilbel, Germany – 10 October 2024 – STADA today announced that the European Medicines Agency (EMA) has accepted for review marketing authorization applications for AVT03, a proposed biosimilar candidate to Prolia® and Xgeva® (denosumab) bone-health and oncology medicines.

Approval is sought for the same indications, dosage form, route of administration and dosing regimen as the respective reference medicines.

Under the terms of a strategic partnership, Alvotech is responsible for the development and manufacturing of AVT03 at its state-of-the-art facility in Reykjavik, Iceland. STADA will become marketing authorization holder, upon European Commission approval of AVT03, and will assume commercial rights in Europe, as well as in selected countries in Central Asia and the Middle East.

STADA's Global Specialty Head, Bryan Kim, commented: "Approval for a denosumab biosimilars would complement the expertise and experience we have gained through our

market-leadership in Europe's teriparatide osteoporosis treatments market. We also look forward to expanding our offering to the oncology community, which we already serve through a broad portfolio that includes a bevacizumab biosimilar."

The European denosumab market is currently valued at approximately €1 billion. Biosimilar competition to Prolia® and Xgeva® could expand patient access considerably at the same or lower overall costs.

An estimated 32 million Europeans, equating to 5.6% of the continent's total population aged 50 years and older, had osteoporosis in 2019.[1] Of these Europeans, around four in five, or 25.5 million, were female. The International Osteoporosis Foundation (IOF) calculates the total direct cost in 2019 of osteoporotic fractures in the 27 European Union member states, Switzerland and the UK at €56.9 billion (US$61.9 billion).

Metastatic bone disease is most commonly seen with specific cancer types — notably those with metastasis from the breast (70%), prostate (85%), lung (40%) and kidney (40%) — as well as multiple myeloma (95%).[2] Bone metastases often cause complications, such as pathological fractures, that are associated with loss of mobility and social functioning, reduced quality of life, increased health care expenditure and worse survival.

About AVT03 (denosumab)

AVT03 is a human monoclonal antibody and a biosimilar candidate to Prolia® and Xgeva® (denosumab). Denosumab targets and binds with high affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction[3]. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

[1] Key statistic for Europe | International Osteoporosis Foundation

[2] Bone health in cancer: ESMO Clinical Practice Guidelines† - Annals of Oncology

[3] Prolia | European Medicines Agency (EMA) (europa.eu)

Use of trademarks
Prolia and Xgeva are registered trademarks of Amgen Inc.

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,734.8 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802.1 million. As of 31 December 2023, STADA employed 11,667 people worldwide.

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