Press Release

STADA further builds its bone-health and oncology offering with positive CMHP opinion on denosumab biosimilars

- European Medicines Agency's CHMP committee recommends approving STADA's Kefdensis® (bone health) and Zvogra® (oncology) denosumab biosimilar candidates for all indications of reference medicines Prolia® and Xgeva® and respectively
- Commission approvals would complement STADA's strong Specialty offering in bone health, including Europe's leading teriparatide biosimilar, as well as its portfolio of oncology medicines such as bevacizumab and epoetin biosimilars
- STADA's Global Specialty Head Ian Henshaw: "This positive CHMP opinion marks a significant step towards broadening access to a blockbuster biologic medicine for bone conditions affecting millions of people in Europe. Building on STADA's European market leadership with biosimilar teriparatide in osteoporosis, as well as our extensive oncology offering, we continue to build strong momentum in our Specialty business segment."

Bad Vilbel, Germany – 19 September 2025 – STADA today received positive opinions from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending that marketing authorizations be granted in Europe for its Kefdensis® and Zvogra® biosimilar denosumab candidates. The CHMP recommended approval for the same indications, route of administration and dosing regimen as the Prolia® (bone health) and Xgeva® (oncology) reference medicines[1].

[1] Kefdensis | European Medicines Agency (EMA); Zvogra | European Medicines Agency (EMA)

Upon the grant of marketing authorizations from the European Commission, denosumab would become STADA's tenth approved Specialty biosimilar. The two denosumab products would join: teriparatide in bone health; bevacizumab in oncology; epoetin zeta in nephrology and oncology; adalimumab, tocilizumab and ustekinumab in immunology; and aflibercept and ranibizumab in ophthalmology.

"This positive CHMP opinion marks a significant milestone in broadening access to a blockbuster biologic medicine for bone conditions affecting millions of people in Europe," commented STADA's Global Specialty Head, Ian Henshaw. "Building on STADA's European market leadership with biosimilar teriparatide in osteoporosis, as well as our extensive oncology offering, we continue to build strong momentum in our Specialty business segment".

Across all indications, the European denosumab market is currently valued at approximately €1 billion. Biosimilar competition to Prolia® and Xgeva® upon anticipated expiry of European Union exclusivity rights in Q4 2025 could expand patient access considerably at the same or lower overall costs.

Kefdensis®, referencing Amgen's Prolia®, received a positive opinion from the CHMP for treating osteoporosis in postmenopausal women and in men at increased risk of fractures. Zvogra®, referencing Amgen's Xgeva®, received a positive opinion from the CHMP for the prevention of skeletal-related events in adults with advanced malignancies involving bone, as well as for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

One in three women and at least one in six men will suffer an osteoporotic fracture in their lifetime, according to the International Osteoporosis Foundation's Scope '21 report[2]. For

[2] SCOPE Summary Report.pdf

every minute that passes, eight new fracture cases arise in the European Union. It is estimated that more than 23 million men and women are at high risk of osteoporotic fractures in the EU.

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%).[3] 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.

Under the terms of a strategic partnership, Alvotech is responsible for the development and manufacturing of the denosumab biosimilars – also referred to as 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. The two companies have already collaborated to bring a high-concentration adalimumab biosimilar and the first EU-approved ustekinumab biosimilar to patients across Europe.

Specialty, including biosimilars, was the fastest-growing of STADA's three business segments in the first half of 2025, with adjusted constant-currency revenues increasing by 18% to €486 million. This rise was largely attributable to a strong performance and penetration of STADA's ustekinumab biosimilar launched from July 2024, reinforced by continued broad-based growth of the group's in-market biosimilars portfolio. Growing patient uptake of innovative nephrology and neurology brands also contributed to the double-digit Specialty revenues growth.

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

About Denosumab

Denosumab is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein in the body called RANKL. RANKL is involved in activating osteoclasts, the cells in the body that are involved in breaking down bone tissue. By attaching to and blocking RANKL, denosumab reduces the formation and activity of the osteoclasts. This reduces the loss of bone and maintains bone strength, making fractures less likely to happen. I osteoclast activity stimulated by RANKL is a key mediator of bone destruction in metastatic bone disease. Denosumab binds to RANKL with high affinity and specificity, preventing the interaction between RANKL and RANK. This leads to a reduction in osteoclast numbers and function, and a decrease in bone resorption and cancer-induced bone destruction.

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 over 100 countries. In financial year 2024, STADA achieved group sales of € 4.059 billion and adjusted constant-currency earnings before interest, taxes, depreciation and amortization (adj. cc EBITDA) of € 886 million. As of 31 December 2024, STADA employed 11,649 people worldwide.

Additional information for journalists

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