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Press Release

Hikma announces launch of Enoby™ (denosumab-qbde) and Xtrenbo™ (denosumab-qbde) referencing Prolia® and Xgeva® respectively

London, 19 January 2026 – Hikma Pharmaceuticals PLC, along with its wholly owned subsidiary Hikma Pharmaceuticals USA Inc. (Hikma) today announced the launch of Enoby™ (denosumab-qbde) and Xtrenbo™ (denosumab-qbde), biosimilar products referencing Prolia® and Xgeva® respectively.

Hikma and Gedeon Richter Plc (Richter) entered into a license and commercialization agreement for Enoby™ and Xtrenbo™, originally known as RGB-14, in 2021. Under the terms of this agreement, Richter is responsible for the manufacture of the products, and Hikma is responsible for exclusive commercialization in the US.

Denosumab is indicated for treating osteoporosis in postmenopausal women, preventing skeletal-related complications in cancer that has spread to the bone, and treating unresectable giant cell tumor of the bone.

“We are excited to have launched our second biosimilar in the US and are proud to be able to bring these biosimilar options to healthcare providers and patients” said Craig Boyd, VP Specialty Products, Injectables. “We are a top-three US provider of sterile injectable medicines to US hospitals and this launch further broadens our portfolio of over 180 injectable products. We look forward to leveraging our strong commercial capabilities to increase affordable access to these important products.”

About Enoby™ and Xtrenbo™ (denosumab-qbde)
Both Enoby™ and Xtrenbo™ contain denosumab, a human monoclonal antibody (IgG2) that targets and binds with high affinity to RANKL, inhibiting its interaction with the RANK receptor on osteoclasts and their precursors. This mechanism prevents osteoclast formation, function, and survival, thereby reducing bone resorption in both cortical and trabecular bone. The products are administered subcutaneously, with dosing regimens and presentations identical to those of the reference medicines.

About Hikma Pharmaceuticals PLC
Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,100 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

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Important Safety Information for ENOBY™ (denosumab-qbde) Injection

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

- **Patients with advanced chronic kidney disease (eGFR <30 mL/min/1.73 m^2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported *[see Warnings and Precautions (5.1)]*.**
- **The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia in these patients *[see Warnings and Precautions (5.1)]*.**
- **Prior to initiating ENOBY™ in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with ENOBY™ in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*.**

CONTRAINDICATIONS

ENOBY™ is contraindicated in:

- Patients with hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with ENOBY™.
- Pregnant women: Denosumab products may cause fetal harm when administered to a pregnant woman. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with ENOBY™.
- Patients with hypersensitivity to denosumab products: ENOBY™ is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling, and urticaria.

WARNINGS & PRECAUTIONS

- **Severe Hypocalcemia and Mineral Metabolism Changes –** Denosumab products can cause severe hypocalcemia and fatal cases have been reported. Patients with advanced chronic kidney disease including dialysis-dependent patients are at greater risk for severe hypocalcemia following denosumab products administration.
- **Drug Products with Same Active Ingredient –** Patients receiving ENOBY™ should not receive other denosumab products concomitantly.
- **Hypersensitivity –** Clinically significant hypersensitivity including anaphylaxis has been reported with denosumab products. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria.
- **Osteonecrosis of the Jaw –** Osteonecrosis of the jaw (ONJ), which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing. ONJ has been reported in patients receiving denosumab products.
- **Atypical Subtrochanteric and Diaphyseal Femoral Fractures –** Atypical low energy or low trauma fractures of the shaft have been reported in patients receiving denosumab products.
- **Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation –** Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures.
- **Serious Infections –** In a clinical trial of over 7,800 women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the denosumab group than in the placebo group.
- **Dermatologic Adverse Reactions –** In a large clinical trial of over 7,800 women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema, and rashes occurred at a significantly higher rate in the denosumab group compared to the placebo group.
- **Musculoskeletal Pain –** In postmarketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking denosumab products.
- **Suppression of Bone Turnover –** In clinical trials in women with postmenopausal osteoporosis, treatment with denosumab resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry.
- **Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta –** ENOBY™ is not approved for use in pediatric patients. Hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated

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with denosumab products. Some cases required hospitalization.

ADVERSE REACTIONS

The most common adverse reactions reported with denosumab products in patients with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis.

The most common adverse reactions reported with denosumab products in men with osteoporosis are back pain, arthralgia, and nasopharyngitis.

The most common adverse reactions reported with denosumab products in patients with glucocorticoid-induced osteoporosis are back pain, hypertension, bronchitis, and headache.

The most common (per patient incidence ≥ 10%) adverse reactions reported with denosumab products in patients with bone loss receiving androgen deprivation therapy for prostate cancer or adjuvant aromatase inhibitor therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

USE IN SPECIFIC POPULATIONS

Pregnancy: ENOBY™ is contraindicated for use in pregnant women because it may cause harm to a fetus. There are insufficient data with denosumab products use in pregnant women to inform any drug-associated risks for adverse developmental outcomes.

Females of Reproductive Potential: Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of ENOBY™.

INDICATIONS AND USAGE

Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture
ENOBY™ is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, denosumab reduces the incidence of vertebral, nonvertebral, and hip fractures.

Treatment to Increase Bone Mass in Men with Osteoporosis
ENOBY™ is indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of Glucocorticoid-Induced Osteoporosis
ENOBY™ is indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of Bone Loss in Men Receiving Androgen Deprivation Therapy for Prostate Cancer
ENOBY™ is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer. In these patients denosumab also reduced the incidence of vertebral fractures.

Treatment of Bone Loss in Women Receiving Adjuvant Aromatase Inhibitor Therapy for Breast Cancer
ENOBY™ is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

ENDING INFORMATION

Patient Counseling Information should be shared with the patient prior to administration.
For additional information, please refer to the Package Insert for full prescribing information, available

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on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800 FDA-1088 or www.fda.gov/medwatch.

Manufactured by:
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Important Safety Information for XTRENBO™ (denosumab-qbde) Injection

CONTRAINDICATIONS

Hypocalcemia
Pre-existing hypocalcemia must be corrected prior to initiating therapy with XTRENBO™.

Hypersensitivity
XTRENBO™ is contraindicated in patients with known clinically significant hypersensitivity to denosumab products.

WARNINGS & PRECAUTIONS

- **Drug Products with Same Active Ingredient –** Patients receiving XTRENBO™ should not receive other denosumab products concomitantly.
- **Hypersensitivity –** Clinically significant hypersensitivity including anaphylaxis has been reported with use of denosumab products. Reactions may include hypotension, dyspnea, upper airway edema, lip swelling, rash, pruritus, and urticaria.
- **Hypocalcemia –** Denosumab products can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Monitor calcium levels throughout XTRENBO™ therapy and administer calcium, magnesium, and vitamin D as necessary. Concomitant use of calcimimetics and other drugs that can lower calcium levels may worsen hypocalcemia risk. An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction and with inadequate/no calcium supplementation.
- **Osteonecrosis of the Jaw –** Osteonecrosis of the jaw (ONJ) has been reported in patients receiving denosumab products, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.
- **Atypical Subtrochanteric and Diaphyseal Femoral Fractures –** Atypical femoral fracture has been reported with denosumab products and most commonly occur with minimal or no trauma to the affected area.
- **Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone and in Patients with Growing Skeletons –** Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in denosumab product-treated patients with giant cell tumor of bone and patients with growing skeletons. Hypercalcemia has been reported within the first year after treatment discontinuation.
- **Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation –** Multiple vertebral fractures (MVF) have been reported following discontinuation of treatment with denosumab products. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures.
- **Embryo-Fetal Toxicity –** Denosumab products can cause fetal harm when administered to a pregnant woman.

ADVERSE REACTIONS

Bone Metastasis from Solid Tumors
The most common adverse reactions were fatigue/asthenia, hypophosphatemia, and nausea.

Multiple Myeloma
The most common adverse reactions were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.

Giant Cell Tumor of Bone
The most common adverse reactions were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.

Hypercalcemia of Malignancy
The most common adverse reactions were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

USE IN SPECIFIC POPULATIONS

Pregnancy: Denosumab products can cause fetal harm when administered to a pregnant woman. There are insufficient data with denosumab product use in pregnant women to inform any drug associated risks for adverse developmental outcomes.

Females of Reproductive Potential: Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of XTRENBO™.

Pediatric Use: The safety and effectiveness of XTRENBO™ have not been established in pediatric patients except in skeletally mature adolescents (aged 12–16 years) with giant cell tumor of bone.

Renal Impairment: Greater risk of developing hypocalcemia was observed with increasing renal impairment, and with inadequate/no calcium supplementation.

INDICATIONS AND USAGE

Multiple Myeloma and Bone Metastasis from Solid Tumors
XTRENBO™ is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

Giant Cell Tumor of Bone
XTRENBO™ is indicated 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.

Hypercalcemia of Malignancy
XTRENBO™ is indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

ENDING INFORMATION

Patient Counseling Information should be shared with the patient prior to administration.
For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

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