Sandoz announces first patient enrolled in clinical study for proposed biosimilar denosumab in osteoporosis

- **Integrated Phase I/III study for proposed biosimilar denosumab to confirm matching efficacy, safety and immunogenicity with reference medicine**¹

- **Osteoporosis accounts for 8.9m bone fractures annually, including debilitating hip fractures -- number set to increase substantially over next two decades**²

- **Sandoz has eight marketed biosimilar medicines globally and 10+ molecules in the pipeline including proposed biosimilar denosumab**

**Holzkirchen, July 22, 2019** – Sandoz, a Novartis division and a global leader in biosimilars, today announced the first patient enrolled in ROSALIA, an integrated Phase I/III clinical study for its proposed biosimilar denosumab.

The study aims to confirm that the biosimilar matches the reference medicine in terms of pharmacokinetics, efficacy, safety, and immunogenicity in patients with postmenopausal osteoporosis¹.

Denosumab is indicated for treating a variety of conditions, such as osteoporosis in postmenopausal women, increased risk of fractures in men, treatment-induced bone loss, to prevent bone complications in cancer that has spread to the bone, and giant cell tumor of the bone³⁴⁵⁶. The study will be conducted in osteoporosis as this is an adequately sensitive indication and representative of many patients who are treated with the medicine.

Approximately 200 million people worldwide suffer from osteoporosis, which results in 8.9 million fractures annually²⁷. By 2050, hip fractures are projected to increase by 240% in women and 310% in men compared to 1990².

“People with the bone disease osteoporosis are more likely to fracture or break a bone, causing pain and restriction of mobility, which can be extremely debilitating⁸," said Florian Bieber, Global Head of Development, Sandoz Biopharmaceuticals. "As we progress our development program for proposed biosimilar denosumab, we believe it gives patients hope for early and expanded access to advanced biologic medicines, which may change the course of their disease.”

In ROSALIA, approximately 520 postmenopausal patients with osteoporosis will be randomized to receive either biosimilar denosumab or the reference medicine for 52 weeks. Following this period, patients receiving the reference medicine will be re-randomized to either continue with a third dose or transition to biosimilar denosumab, until 78 weeks of treatment. The primary endpoints include percentage change in lumbar spine bone mineral density¹. The
global clinical program for biosimilar denosumab was developed in consultation with major regulatory agencies and the results from this clinical study are expected to support regulatory submissions.

Sandoz biosimilars are helping patients, particularly in immunology, oncology and endocrinology, access medicines sustainably and affordably. The division has a leading global portfolio with eight marketed biosimilars and a further 10-plus in various stages of development. The Sandoz biosimilar pipeline is a blend of in-house development and collaborations, both for co-development and commercialization, targeting key biologics in oncology, immunology, endocrinology and underserved complex disease areas.

About denosumab

Denosumab is a monoclonal antibody designed to recognize and attach to the RANKL protein, an activator of osteoclasts (cells involved in breaking down bone tissue). By attaching 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 complications.

Disclaimer

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About Sandoz
Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars and a pioneer in the emerging field of prescription digital therapeutics. Our purpose is to pioneer access to healthcare by developing and commercializing novel, affordable approaches that address unmet medical need. Our broad portfolio of high-quality medicines, covering all major therapeutic areas and increasingly focused on value-adding differentiated medicines, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz global at [http://twitter.com/Sandoz_Global](http://twitter.com/Sandoz_Global).

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