Press Release

FDA approves Lucamzi biosimilar to Lucentis

- Lucamzi™ (ranibizumab-blrz), a biosimilar to Lucentis®, approved by the FDA, further strengthening STADA's Specialty presence in the US
- STADA will work with its partners to bring further competition in the ophthalmic therapeutic space, providing equivalent therapeutic value at reduced costs, thereby improving patient access for serious eye conditions
- STADA Chief Commercial Officer Bryan Kim: "Bringing ranibizumab to the US builds upon the improved patient access we have achieved in Europe with our Ximluci ranibizumab biosimilar, one of 12 marketed or approved biosimilars in STADA's expanding biosimilars portfolio."

Bad Vilbel, Germany – 29 October 2026 – American ophthalmologists and their patients will soon have a cost-effective treatment option for neovascular wet age-related macular degeneration (wAMD) and other serious eye conditions, following approval by the US Food and Drug Administration (FDA) of Lucamzi™ (ranibizumab-blrz) as a biosimilar to Lucentis® [1].

The FDA rigorously reviews biosimilars based on the totality of the evidence presented by the sponsor, so that healthcare providers and patients can be confident of their safety, effectiveness and quality. For Lucamzi, this evidence was based on a comprehensive comparative analytical assessment atstructural and functional levels, as well as a Phase 3 clinical study in 582 patients with wAMD that demonstrated equivalent efficacy and comparable safety to the reference product.[2]

[1] Drugs@FDA: FDA-Approved Drugs

[2] Study Results | NCT03805100 | Comparing the Efficacy and Safety of Biosimilar Candidate Xlucane Versus Lucentis® in Patients With nAMD | ClinicalTrials.gov

Executive Board: Peter Goldschmidt (CEO) / Miguel Pagan Fernandez / Boris Döbler / Bryan Kim
Chairman of the Supervisory Board: Dr. Günter von Au

STADA is now, together with its partners, finalizing preparations for the commercial launch of Lucamzi in the United States.

“Bringing ranibizumab in the US builds upon the improved patient access we have achieved in Europe with our Ximluci ranibizumab biosimilar, one of 12 marketed or approved biosimilars within STADA’s expanding biosimilars portfolio,” highlighted STADA’s Chief Commercial Officer, Bryan Kim. ”It also expands STADA’s growing presence in the US specialty pharmaceuticals market, adding to our existing partnerships in therapeutic categories such as Parkinson’s disease with apomorphine and oncology with epoetin.”

Ranibizumab is an anti-VEGF (vascular endothelial growth factor) drug for treating retinal vascular disorders, which are a leading cause of blindness globally. Around 20 million people in the US are living with any form of AMD, with an age-standardized prevalence of 5,677 per 100,000 people.[3] The total economic burden of late-stage wet AMD in the US is estimated at between $19.7 billion annually, based on a mid-value prevalence rate.[4] Increased biosimilar competition on ranibizumab, including through Lucamzi, provides cost-effective options to provide equivalent therapy at lower prices, thereby helping to reduce US healthcare costs and improve patient access.

About STADA

STADA is headquartered in Bad Vilbel, Germany. The group focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA sells its products in over 100 countries. In financial year 2025, STADA achieved group sales of € 4,296 million. As of 31 December 2025, STADA employed 11,670 people worldwide.

[3] Prevalence and Health Care Disparities of Retinal Conditions: A Meta-Analysis | Ophthalmology | JAMA Ophthalmology | JAMA Network; Published Online: 19 March 2026

[4] Economic Burden in Late-Stage AMD High in Patients and Caregivers in US | AJMC; Published 6 November 2024

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