Press Release

STADA Expands Specialty Biosimilars Portfolio through European Approval for Afiveg (aflibercept)

- European Commission grants STADA marketing authorization for Afiveg® (aflibercept) pre-filled syringes and vials, marking STADA's second approved biosimilar in ophthalmology
- Launch in lead market Germany is scheduled following expected loss of EU protection for the Eylea® reference product in Q4 2025
- STADA Global Specialty Head Ian Henshaw: "We look forward to building on the credibility we have built in the specialty ophthalmology sector through our biosimilar ranibizumab to expand patient access to aflibercept."

Bad Vilbel, Germany – 16 September 2025 – STADA has expanded its Specialty portfolio of approved biosimilars in Europe to eight molecules. The European Commission has granted STADA marketing authorization for Afiveg® (aflibercept), a biosimilar to the Eylea® reference product, as 40mg/ml solution for injection in pre-filled syringes and vials.

Approval from the Commission follows the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) positive opinion in June 2025 recommending approval of Afiveg to treat multiple retinal diseases, including neovascular (wet) age-related macular degeneration (AMD)[1]. STADA anticipates introducing the biosimilar in its lead market, Germany, following expected loss of exclusivity for the Eylea reference brand during the fourth quarter of 2025.

[1] Afiveg | European Medicines Agency (EMA)

Afiveg is STADA's second ophthalmology biosimilar approved in Europe, joining Ximluci (ranibizumab), which STADA now offers in more than 20 countries, holding top-three market positions, measured by revenues in the 12 months ended June 2025, in 15 European countries. Afiveg is also the Group's eighth approved biosimilar overall. It adds to approvals for epoetin zeta in nephrology and oncology, teriparatide in bone health, adalimumab, tocilizumab and ustekinumab in immunology; bevacizumab in oncology; and ranibizumab in ophthalmology.

"We look forward to building on the credibility in the specialty ophthalmology sector we have built with biosimilar ranibizumab to expand patient access to aflibercept in treating retinal conditions that affect millions of people," stated STADA's Global Specialty Head, Ian Henshaw. "We will work closely with ophthalmologists, clinicians and other stakeholders to improve patient access to biologic treatment options as a trusted supplier of effective, high-quality biosimilars."

Specialty 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.

About Afiveg (aflibercept)
Afiveg is a biosimilar medicinal product that is highly similar to the reference product Eylea, which was authorised in the EU on 22 November 2012. The active substance of Afiveg is aflibercept, an antineovascularisation agent (ATC code: S01LA05). Aflibercept is a recombinant fusion protein consisting of the extracellular domains of human VEGF receptor 1 and 2 fused to the Fc portion of human IgG1. By acting as a soluble decoy for the natural VEGF receptors, aflibercept inhibits their activation, thereby reducing angiogenesis. Data show that Afiveg has comparable quality, safety and efficacy and immunogenicity to the reference product.

Afiveg is indicated for the treatment of adults with: neovascular (wet) age-related macular degeneration ((w)AMD); visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO); visual impairment due to diabetic macular oedema (DME); and visual impairment due to myopic choroidal neovascularisation (myopic CNV). Afiveg must only be administered by a qualified physician experienced in administering intravitreal injections.

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 million 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.

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