

## MEDIA RELEASE

## Sandoz receives European Commission approval for Afqilir® (aflibercept), further strengthening leading biosimilar portfolio

- Afqilir® (aflibercept) approved to treat various retinal diseases, including neovascular age-related macular degeneration (nAMD)
- One of several biosimilar value drivers for Sandoz
- Sandoz remains committed to accelerating patient access by strengthening its biosimilar portfolio, reinforcing global and European leadership

**Basel, November 15, 2024** – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in generic and biosimilar medicines, today announced that the European Commission (EC) has granted marketing authorization for Afqilir® (aflibercept) 2 mg vial kit and pre-filled syringe for intravitreal injection, a biosimilar to reference medicine Eylea®\*.<sup>1,2</sup> Afqilir® is indicated to treat various retinal diseases, including neovascular age-related macular degeneration (nAMD), aiming to prevent disease-related blindness.

Afqilir® is one of several biosimilar value drivers for Sandoz and this approval represents a major step in advancing the company's growth strategy. Launch is expected as of Q4 2025.

“Vision loss significantly affects daily activities, from work to social interactions. Early and expanded access to effective treatments is essential for patients to maintain and improve their visual acuity. The approval of Afqilir® is a pivotal moment in delivering an affordable and effective treatment option to patients in Europe who are affected by conditions such as nAMD. This milestone underscores our commitment to improving patient outcomes through accessible, high-quality biosimilars.”

**Claire D'Abreu-Hayling,  
Chief Scientific Officer,  
Sandoz**



nAMD is a subtype of AMD, characterized by a vision loss in the central zone, and is a leading cause of vision impairment in patients over 65 years of age.<sup>3</sup> nAMD accounts for approximately 10 to 20% of all AMD cases, but is responsible for 90% of the severe vision loss due to AMD.<sup>4</sup> A study found that the prevalence of

nAMD in France, Germany, Italy, Spain, the UK, the US and Japan is around 3.6 million patients, of which 2.5 million are diagnosed and only 1.7 million receive treatment.<sup>5</sup>

\*Eylea® is a registered trademark of Bayer AG.

## About Afqilir® (aflibercept)

The active ingredient in Afqilir® is aflibercept. Aflibercept is a recombinant fusion protein that binds to vascular endothelial growth factor A (VEGF-A) and placental growth factor (PlGF), inhibiting abnormal vessel growth. Aflibercept is injected into the eye to improve visual acuity and inhibit disease progression. The robust biosimilar development program of Afqilir® consisted of a comprehensive package including analytical and preclinical in vitro study data, as well as clinical data from the Mylight study, and confirmed that Afqilir® has equivalent efficacy and comparable safety to its reference medicine.

Afqilir® is indicated to improve and maintain visual acuity in patients with neovascular age-related macular degeneration (nAMD), macular oedema following retinal vein occlusion (RVO), diabetic macular oedema (DME) and myopic choroidal neovascularisation (mCNV).<sup>1</sup>

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This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly revise any forward-looking statements, except as required by law.

## REFERENCES

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4. Quillen DA. *Am Fam Physician.* 1999;60(1):99-108.
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## ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 800 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,500 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2023, Sandoz recorded net sales of USD 9.6 billion.

# SANDOZ

## CONTACTS

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### Global Media Relations contacts

**Global.MediaRelations@sandoz.com**

Joerg E. Allgaeuer  
+49 171 838 4838

Chris Lewis  
+49 174 244 9501

Gregor Rodehueser  
+49 170 574 3200

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### Investor Relations contacts

**Investor.Relations@sandoz.com**

Laurent de Weck  
+41 79 795 7364

Tamara Hackl  
+41 79 790 5217

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