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MEDIA & INVESTOR RELEASE

Sandoz announces positive results from Mylight Phase III study for biosimilar aflibercept

- *Mylight study met its primary efficacy endpoint and showed no clinically meaningful differences to reference aflibercept*
- *Results offer hope of new affordable option for patients with nAMD, a leading cause of visual impairment and progressive vision loss for older adults*[1]
- *Aflibercept is one of four high-value biosimilars that Sandoz plans to launch over next few years, further expanding patient access to high-quality biologics*

Basel, August 15, 2023 — Sandoz, a global leader in off-patent medicines, today releases positive results from the MYLIGHT Phase III confirmatory efficacy and safety study for its biosimilar aflibercept, for patients living with wet macular degeneration – a key development in its efforts to address this area of unmet medical need.

Mylight (ClinicalTrials.gov NCT04864834) is part of a comprehensive biosimilar development program that encompasses analytical, preclinical, and a clinical study. The Mylight Phase III confirmatory efficacy and safety study met its primary efficacy endpoint, showing therapeutic equivalence in mean change of best corrected visual acuity (BCVA) from baseline to week 8 between the biosimilar aflibercept and the reference biologic, Eylea®. Safety, immunogenicity, and pharmacokinetics results further confirm that there is no clinically meaningful difference between the products.

The reference product Eylea® is indicated to improve and subsequently maintain visual acuity in patients with Neovascular Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema, macular edema secondary to Retinal Vein Occlusion (RVO), and other specific neovascular retinal diseases. [2] These conditions cause blurring of central vision and, if untreated, can lead to permanent vision loss. nAMD affects over 200 million people worldwide and is one of the most widespread causes of blindness.[3]

Claire D'Abreu-Hayling, Chief Scientific Officer, Sandoz, said: "This important milestone, confirming therapeutic equivalence of the biosimilar aflibercept with the reference biologic, takes us one step closer to providing patients with a key treatment in an area of high unmet need within ophthalmology. It also underscores our ability to provide high-quality, affordable biologics to individuals to help the treatment of their disease, and highlights the rich Sandoz pipeline of biologics."

Sandoz is committed to helping millions of patients by providing affordable access to critical and potentially life-changing biologic medicines across a wide range of therapeutic areas including ophthalmology, immunology, oncology, supportive care, and endocrinology. It has a leading global portfolio with eight marketed biosimilars and a further 24 assets in various stages of development. Since launching the first biosimilar in Europe in 2006, Sandoz has demonstrated that biosimilars can significantly expand patient access to highly effective and

safe medicines while increasing healthcare savings and creating competition that fuels innovation and development of new and enhanced treatments in areas of unmet need.

Sandoz expects to file for regulatory approval for biosimilar aflibercept in the US and EU in the coming months.

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About 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. In patients with neovascular retinal diseases, like neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), or retinal vein occlusion (RVO), aflibercept is injected into the eye to improve visual acuity and inhibit disease progression.

About Mylight
Mylight is a randomized, double-masked, parallel 2-arm study, which enrolled 485 patients across 16 countries. The Mylight study was conducted in nAMD (wet/exudative) as this is an

adequately sensitive indication to demonstrate therapeutic equivalence to the reference biologic, Eylea®.[2] Neovascular AMD patients were randomized 1:1 to receive either biosimilar aflibercept or Eylea® for 48 weeks followed by a safety follow-up period of four weeks. The total study duration was 52 weeks. The primary endpoint is the mean change in best corrected visual acuity (BCVA) score from baseline to week 8, using a standard test chart (EDTRS).

The global development program for Sandoz biosimilar aflibercept was developed in consultation with major regulatory agencies and the results from this clinical study are expected to support regulatory submissions.

*Eylea® is a trademark of Bayer AG and in the US of Regeneron Pharmaceuticals, Inc.

About Sandoz
Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our vision is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines covers major therapeutic areas.

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CEO Richard Saynor on LinkedIn: https://www.linkedin.com/in/richard-saynor/

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