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Sandoz confirms late-stage clinical development plans for proposed biosimilar aflibercept, a key ophthalmology medicine

- *Sandoz to begin enrolling patients with neovascular age-related macular degeneration in MYLIGHT Phase lll confirmatory efficacy and safety study*[1]
- *Neovascular age-related macular degeneration accounts for 10% of age-related macular degeneration cases, but is responsible for 90% of AMD-related blindness*[2]
- *With eight marketed biosimilar medicines globally and 15+ molecules in pipeline, Sandoz is investing in future of biosimilars for patients and healthcare systems*

Holzkirchen, May 3, 2021 – Sandoz, a Novartis division, today announced progress in the late-stage clinical development program for its proposed biosimilar aflibercept. Sandoz will begin enrolling the first patient in MYLIGHT, a clinical Phase III confirmatory efficacy and safety study, shortly[1].

Aflibercept is indicated to improve visual acuity in patients with neovascular age-related macular degeneration (nAMD), diabetic macular oedema, macular oedema secondary to retinal vein occlusion, and other specific neovascular retinal diseases[3].

“nAMD accounts for 10% of all age-related macular degeneration cases, but is responsible for 90% of AMD-related blindness[2],” said Florian Bieber, Global Head of Biopharmaceuticals Development, Sandoz. “Aflibercept is a key treatment in ophthalmology. The initiation of this study marks an important milestone in the development of our biosimilar aflibercept. As with all our biosimilar programs, we aim to expand access to high-quality, more affordable biologics.”

MYLIGHT is part of a comprehensive biosimilar development program including analytical, preclinical and clinical data. The study aims to confirm that the proposed biosimilar has equivalent efficacy and comparable safety to the reference medicine* in patients with nAMD[1].

Sandoz biosimilars help patients to access advanced biologic medicines more sustainably and affordably. The Sandoz division has a leading global portfolio with eight marketed biosimilars and a further 15-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 aflibercept

Aflibercept binds and inhibits ocular VEGF-A, and prevents abnormal growth of blood vessels in the choroid which impact visual function. It improves visual acuity in patients with neovascular retinal diseases like nAMD, Diabetic macular edema (DME), and Retinal vein occlusion (RVO).

About MYLIGHT

The MYLIGHT is a randomized, double-blind, parallel 2-arm study, which is projected to include 460 patients across 20 countries. The MYLIGHT study will be conducted in neovascular (wet) age-related macular degeneration as this is an adequately sensitive indication and representative of many patients who are treated with the medicine.[1] nAMD patients will be randomized to receive either biosimilar aflibercept or the reference medicine for 48 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.

Disclaimer

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obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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 ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2020 sales of USD 9.6 billion.

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