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
• 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. 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.

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.

**Disclaimer**
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such generic or biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

---

**About aflibercept**
Aflibercept is a recombinant fusion protein that binds to vascular endothelial growth factor A (VEGF-A) and placental growth factor (PIGF), 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®. 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.

Sandoz on social media:
LinkedIn: https://www.linkedin.com/company/sandoz
Twitter: https://twitter.com/sandoz_global
Facebook: https://www.facebook.com/sandozglobal/
Instagram: https://www.instagram.com/sandozglobal

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

# # #

References

# # #

Sandoz Global Communications

Central
Chris Lewis +49 174 244 9501

North America
Leslie Pott +1 609 627 5287

Novartis Media Relations
E-mail: media.relations@novartis.com

Central
Richard Jarvis +41 79 584 2326

North America
Julie Masow +1 862 579 8456

Switzerland
Satoshi Sugimoto +41 79 619 2035
**Novartis Investor Relations**
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

<table>
<thead>
<tr>
<th>Central</th>
<th></th>
<th>North America</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Samir Shah</td>
<td>+41 61 324 7944</td>
<td>Sloan Simpson</td>
<td>+1 862 345 4440</td>
</tr>
<tr>
<td>Nicole Zinsli-Somm</td>
<td>+41 61 324 3809</td>
<td>Parag Mahanti</td>
<td>+1 973 876 4912</td>
</tr>
<tr>
<td>Isabella Zinck</td>
<td>+41 61 324 7188</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>