



Bayer AG  
Communications  
51368 Leverkusen  
Germany  
Phone +49 214 30-1  
[www.bayer.com/en/media](http://www.bayer.com/en/media)

## News Release

**Not intended for U.S. and UK Media**

---

### **Aflibercept 8 mg in diabetic macular edema first to achieve sustained vision gains with up to 83% of patients extended to 16-24 weeks at two years**

- Data from pivotal PHOTON trial demonstrate long term efficacy of aflibercept 8 mg with extended intervals comparable to Eylea™ (aflibercept 2 mg) at fixed 8-weekly dosing over two years
  - Patients assigned to a 16-week dosing regimen at baseline received a mean of 7.8 injections (6 fewer than Eylea)
  - Safety profile of aflibercept 8 mg in diabetic macular edema (DME) remains comparable to Eylea with no new signals identified
  - Two-year data from PULSAR to study aflibercept 8 mg in patients with neovascular (wet) age-related macular degeneration (nAMD) expected during the second half of 2023
- 

**Berlin, June 29, 2023** – Bayer today announced the two-year (96 weeks) topline results of the pivotal clinical trial PHOTON investigating its novel aflibercept 8 mg with extended dosing regimens of up to 24 weeks in diabetic macular edema (DME) compared to the current standard of care Eylea™ (aflibercept 2 mg) with fixed intervals of 8 weeks. The two-year results reinforce the long-term efficacy and safety and the unprecedented durability of aflibercept 8 mg in patients with DME.

At two years (96 weeks), the aflibercept 8 mg groups demonstrated that 89% of patients maintained a  $\geq 12$ -week dosing interval, compared to 93% through one year (48 weeks). A considerable number of patients met the extension criteria for dosing intervals greater than every 16 weeks, including 43% reaching  $\geq 20$ -week intervals and 27% reaching 24-week intervals.

Of those randomized to a 16-week dosing regimen at baseline, 83% maintained  $\geq 16$ -week dosing intervals through two years, compared to 89% maintaining a 16-week dosing interval through one year. This group received at 96 weeks 6 fewer injections into the eye, down to a mean number of 7.8 injections versus 13.8 injections with Eylea (aflibercept 2 mg) at fixed 8-weekly dosing. At the same time, extended treatment intervals with aflibercept 8 mg achieved sustained vision gains and safety similar to standard of care Eylea (aflibercept 2 mg).

"We are excited to see that aflibercept 8 mg allowed an unprecedented proportion of patients to be extended to treatment intervals of up to 24 weeks during two years of treatment with outcomes that were consistent with the Eylea 2 mg comparator arm," said Sobha Sivaprasad, Professor and Consultant Ophthalmologist, Moorfields Eye Hospital, London, UK, and member of the steering committee of the PHOTON study. "These clinically important results show that the burden of disease can be reduced for many more patients in the future contributing to improved adherence and thus better patient outcomes."

"Diabetic macular edema is a leading cause of vision loss, and we are fully committed to support patients with extended treatment intervals to alleviate their disease burden," said Dr. Christian Rommel, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of Research and Development. "The current data underline that aflibercept 8 mg provides sustained disease control with greater and longer-lasting control of the underlying disease compared to Eylea in a fixed dosing regimen."

The pivotal clinical trial PHOTON has shown that aflibercept 8 mg met its primary endpoint achieving non-inferior improvements in best corrected visual acuity (BCVA) with extended treatment intervals of up to every 12 or 16 weeks following 3 initial monthly doses, compared to Eylea (aflibercept 2 mg) dosed every 8 weeks following 5 initial monthly doses, throughout the first year of treatment. Now, the two-year data reinforce the efficacy, safety, and durability of aflibercept 8 mg in DME with extended dosing intervals.

In the trial, patients randomized at baseline to receive 12- or 16-week dosing regimens, after only three initial monthly loading doses, were able to shorten or extend to longer dosing intervals in the second year without compromising vision if pre-specified criteria were met.

The safety profile of aflibercept 8 mg was similar to the well-established safety profile of Eylea and consistent with the safety observed in previous clinical trials.

The two-year data from the PULSAR study of aflibercept 8 mg in nAMD are expected during the second half of 2023 and both data sets are planned for presentation at an upcoming scientific congress in 2023.

Aflibercept 8 mg is being jointly developed by Bayer and Regeneron. Regeneron maintains exclusive rights to Eylea and aflibercept 8 mg in the United States. Bayer has licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of Eylea.

Aflibercept 8 mg is investigational, and its safety and efficacy have not yet been fully evaluated by any regulatory authority outside of the U.S.

#### **About PULSAR and PHOTON**

PULSAR and PHOTON are double-masked, active-controlled pivotal trials. Both trials were conducted in multiple centers globally with similar designs and endpoints. The Phase III PULSAR trial in nAMD and Phase II/III PHOTON trial in DME evaluated the efficacy and safety of aflibercept 8 mg with 12- and 16-week dosing regimens versus Eylea (aflibercept 2 mg) dosed every 8 weeks, following initial monthly doses, with the primary endpoint of non-inferiority in terms of best corrected visual acuity (BCVA) at week 48. The two-year data mark the end of the masked study (week 96) with the option to extend treatment intervals up to 24 weeks and with an optional 1-year open-label extension for patients until week 156. Patients in both clinical trials were randomized at baseline to the three different arms. Across both studies, 1,164 patients were treated with aflibercept 8 mg. All patients in the aflibercept 8 mg arms were continuously evaluated under stringent, clinically relevant, patient focused dose regimen modification (DRM) criteria starting from week 16 throughout the study. In the first year, patients in the aflibercept 8 mg groups could have their dosing intervals shortened down to an every 8-week interval if DRM criteria for disease progression were observed. Intervals could not be extended until the second year of the study. In the second year, patients in the aflibercept 8 mg groups could have their dosing intervals shortened or extended if DRM criteria were met. Patients in all Eylea (aflibercept 2 mg) groups maintained a fixed 8-

week dosing regimen throughout their participation in the trials. The lead sponsors of the trials were Bayer for PULSAR and Regeneron for PHOTON.

### **About DME**

Diabetic macular edema (DME) is a common complication in eyes of people living with diabetes. DME occurs when high levels of blood sugar lead to damaged blood vessels in the eye that leak fluid into the macula. This can lead to vision loss and, in some cases, blindness. Globally, 146 million people are currently living with diabetic retinopathy (DR), which can develop into a more serious condition which is diabetic macular edema. DME is affecting around 21 million people globally.

### **About Bayer**

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to [www.bayer.com](http://www.bayer.com).

#### Contact for media inquiries:

**Jutta Schulze, phone +49 175 3002905**

Email: [jutta.schulze@bayer.com](mailto:jutta.schulze@bayer.com)

#### Contact for investor inquiries:

**Bayer Investor Relations Team, phone +49 214 30-72704**

Email: [ir@bayer.com](mailto:ir@bayer.com)

[www.bayer.com/en/investors/ir-team](http://www.bayer.com/en/investors/ir-team)

Find more information at <https://pharma.bayer.com/>

Follow us on Facebook: <http://www.facebook.com/bayer>

Follow us on Twitter: [@BayerPharma](https://twitter.com/BayerPharma)

js

(2023-0116e)

**Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.