# First biosimilar approved for macular degeneration, other eye conditions

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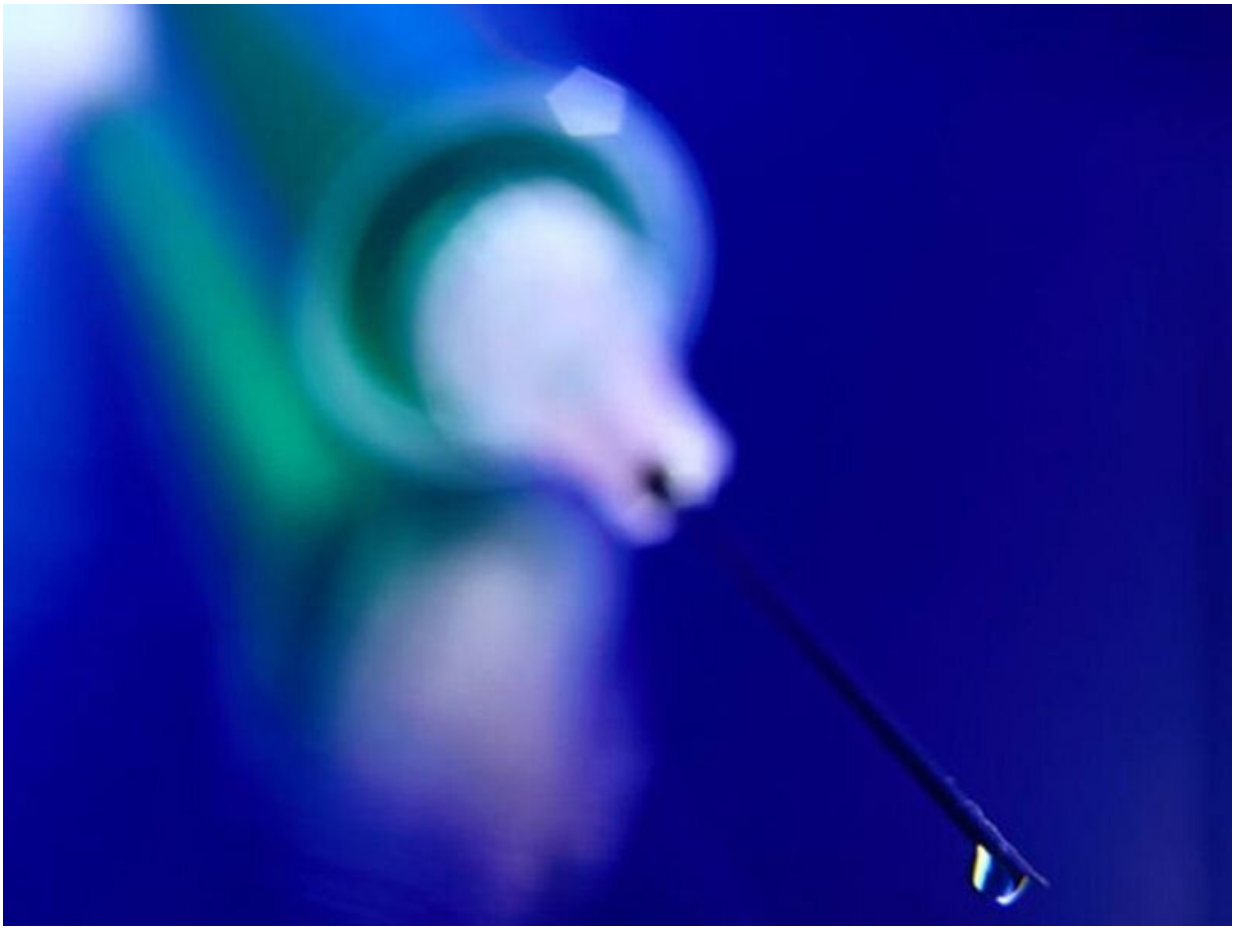

(HealthDay)—The first biosimilar to Lucentis (ranibizumab injection)

has been approved for the treatment of neovascular (wet) age-related macular degeneration and other eye diseases and conditions, the U.S. Food and Drug Administration announced Friday.

The approval of the biosimilar, Byooviz (ranibizumab-nuna), is also indicated to treat macular edema after retinal vein occlusion and myopic choroidal neovascularization. Byooviz is administered monthly through intravitreal injection.

Approval was based on a data review that included "extensive structural and functional characterization, comparative clinical efficacy and safety evaluations, including potential immunogenicity that demonstrated Byooviz is biosimilar to Lucentis," the FDA wrote in a press release.

Potential serious side effects caused by Byooviz administration include endophthalmitis and retinal detachments, increased intraocular pressure, and thromboembolic events. The most commonly reported side effects included conjunctival hemorrhage, eye pain, vitreous floaters, and increased intraocular fluid pressure.

The FDA has so far approved 31 biosimilars for the treatment of various health conditions. "Continuing to grow the number of biosimilar approvals is a key part of our efforts to provide greater access to treatment options for patients, increase competition and potentially lower costs," Sarah Yim, M.D., director of the Office of Therapeutic Biologics and Biosimilars in the FDA Center for Drug Evaluation and Research, said in the press release.

**More information:** More Information