

FDA panel unanimously backs Regeneron eye drug

June 17 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- A panel of federal health experts voted unanimously in favor of a new eye drug from Regeneron, bringing the company one step closer to competing against a blockbuster Roche drug that currently dominates the market.

A [Food and Drug Administration](#) advisory panel voted 10-0 Friday that Regeneron's drug is a safe and effective treatment for a condition that can lead to blindness in seniors, according to an agency spokeswoman. More than 200,000 new cases of the condition, called wet macular degeneration, are diagnosed each year.

The FDA is not required to follow the group's advice, though it often does.

If approved, Regeneron's [injectable drug](#) will be the first product to compete with Roche's Lucentis, which posts sales of \$1.5 billion annually. The FDA is scheduled to make its final decision on approval by Aug. 20. If approved, Regeneron and its partner Bayer Pharmaceuticals will co-market the drug under the brand name Eylea.

Analysts have high expectations for Regeneron's drug because it requires fewer injections than Lucentis: once every two months, versus once a month. Company executives say the extended dosing regimen should appeal to both doctors and patients.

Shares of Tarrytown, N.Y.-based Regeneron Pharmaceuticals Inc. were

halted from trading pending the panel vote.

Wet, [age-related macular degeneration](#) is the most common cause of blindness among older Americans. The condition causes new blood vessels to grow in the eye and leak blood and fluid, damaging the retina and distorting vision.

The "dry" form of the condition is the most common type of macular degeneration, with the "wet" form considered the more advanced version of the disease.

Regeneron may face its toughest competition from another Roche drug called Avastin, which is chemically similar to Lucentis. Avastin is a cancer drug that doctors have used for many years to treat the eye disease even though it is not approved for that purpose. Specially-formulated injections of [Avastin](#) cost just \$50, compared with \$2,000 for [Lucentis](#).

Regeneron executives have not yet discussed how they will price their drug.

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