FDA approves Regeneron's eye injection Eylea

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(AP) -- Regulators on Friday approved Regeneron Pharmaceuticals Inc.'s drug Eylea, an injection designed to treat a common cause of blindness in older people.

Eylea is intended to treat neovascular or "wet" age-related macular degeneration. More than 200,000 cases are diagnosed in the U.S. every year. The standard treatment for the condition is Roche's Lucentis, which was approved in 2006 and posts $1.5 billion in annual sales.

Analysts have high expectations for Eylea because clinical trial data showed it could be administered every other month, although the Food and Drug Administration recommends monthly injections for the first three months and then bimonthly.

Lucentis is approved to be used once per month, although Roche says the drug is often used less frequently.

Regeneron said it will launch Eylea next week. Each dose will cost $1,850, while Lucentis costs $2,000. The company said health insurers and programs like Medicare will save money because patients won't have to visit their doctor as often for injections and checkups. It said those visits cost $250 to $300 each.

Earlier this year, clinical trial data showed Roche's cancer drug Avastin, which is chemically similar to Lucentis, was as effective as Lucentis. A specialty-formulated injection of Avastin costs $50.

Separately, on Friday the FDA withdrew its approval to market Avastin to treat breast cancer because of concerns that the drug's side effects were too great and that it didn't help enough, although it will remain on the market for certain colon, lung, kidney and brain cancers

The most common side effects of Eylea included bleeding of the conjunctiva, eye pain, cataracts, detachment of the retina from the vitreous humor, and greater pressure within the eye. In a few patients, strokes, nonfatal heart attacks, and vascular death, including deaths of unknown cause, occurred. Those side effects occurred in about 1.8 percent of patients combined.

An FDA advisory panel unanimously recommended approval for Eylea in June, but in August, the FDA extended its review of the drug by three months to check additional data.

If the drug is approved in other markets, Bayer HealthCare will market Eylea and the companies will split the profits.

Shares of Regeneron fell $1.32, or 2.6 percent, to close at $49.81before the company announced the FDA approval. The stock picked up 54 cents to $50.35 in aftermarket trading.