

FDA panel backs Pfizer drug for kidney cancer

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(AP) -- A panel of advisers to the Food and Drug Administration voted Wednesday that the benefits of a Pfizer kidney cancer drug outweigh its risks, according to a company spokeswoman.

The unanimous vote came despite FDA concerns that the drug's benefit may have been limited to a subset of patients previously treated with other <u>cancer drugs</u>.

The FDA's panel of 13 cancer experts backed the benefits of Pfizer's axitinib for kidney cancer patients who have not responded well to at least one other drug. The agency is not required to approve drugs backed by the panel, though it often does.

<u>Pfizer Inc.</u> is seeking FDA approval to market the drug for advanced <u>renal cell carcinoma</u>, the most common type of kidney cancer. Studies submitted by the company showed patients on axitinib experienced two more months without their cancer worsening than patients taking <u>Nexavar</u>, a drug from Bayer and Onyx Pharmaceuticals.

But in a scientific review published ahead of the meeting, FDA experts questioned whether the benefit, known as progression-free survival, was driven by other drugs used by some patients.

FDA scientists noted that the slowdown in cancer progression was mainly seen in patients who had already been treated with cytokines, a class of cancer medications that are no longer widely used in the U.S.



and Europe. Patients taking a more common medication called sunitinib only experienced a month and a half without their cancer worsening.

The New York-based company studied its drug in 723 advanced kidney cancer patients from North America, Europe, Asia and elsewhere.

The FDA is expected to make a final decision on whether to approve the drug in the first quarter of next year.

The market for kidney cancer drugs has grown increasingly crowded in recent years, with six new drugs approved in the last six years, including Roche's Avastin and GlaxoSmithKline's Votrient. If approved, Pfizer's drug would only be second designated as a backup, or second-line, treatment after other kidney cancer drugs have been prescribed.

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