FDA questions safety of Glaxo kidney cancer drug

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(AP) -- Federal regulators said Thursday an experimental kidney cancer drug from GlaxoSmithKline may cause liver problems, potentially outweighing its ability to slow the disease.

London-based Glaxo wants the Food and Drug Administration to approve its pazopanib pills for advanced kidney cancer, a rare but deadly form of the disease.

In documents posted online, FDA reviewers noted three deaths related to liver damage with the drug, as well as elevated levels of enzymes that often predict liver damage.

The findings "strongly suggest that pazopanib may be associated with a significant risk of severe idiosyncratic hepatic injury if used in a larger patient population," according to the agency's review.

Along with liver risks, FDA scientists also noted side effects common to other cancer drugs, including hypertension, internal bleeding and blood clots.

The FDA will ask a panel of experts Monday whether pazopanib should be approved, though the negative tone of the agency's review suggests Glaxo faces an uphill battle. The FDA is not required to follow the group's advice, though it usually does.

Glaxo will make the case Monday that its drug could still be a useful option for patients, despite safety concerns and a variety of drugs already on the market.

"GSK will present an overview of a complete package of clinical data that demonstrates how this medicine may benefit patients with this serious disease," the company said in a statement.

When Glaxo began developing its drug there were few treatment options for advanced kidney cancer, which killed about 13,000 people in the U.S. last year, according to the American Cancer Society.

But since 2005, the FDA has approved five new treatments for the disease, including Pfizer's Sutent and Bayer's Nexavar. Glaxo did not compare its drug to these treatments because they were not widely available when the company began designing a trial in 2005.

Instead, the company compared pazopanib to placebo, or a dummy pill. Results from that 435-patient study showed patients taking the drug experienced a five-month halt in the progression of their cancer, though they did not live significantly longer.

The British drugmaker already markets the breast cancer pill Tykerb, which had sales of $189 million last year.