

FDA expands approval of Bayer cancer drug (Update)

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The U.S. Food and Drug Administration on Monday expanded approval of a Bayer cancer pill to treat tumors of the intestinal tract that do not respond to other treatments.

The drug is called Stivarga and regulators approved it to treat gastrointestinal stromal tumors that cannot be surgically removed and no longer respond to other FDA-approved drugs.

The FDA previously approved Stivarga to treat colorectal cancer. It works by blocking several enzymes that promote cancer growth.

The FDA approved the drug for the new use based on a study of nearly 200 patients who were randomly assigned to take Stivarga or a placebo pill.

Patients taking the drug experienced a nearly four month delay in the growth of their tumors compared to taking placebo.

The most common side effects of Stivarga in clinical trials included liver damage, severe bleeding, blistering and peeling of skin, high blood pressure, heart attacks and perforations.

Other drugs approved to treat intestinal tumors include Gleevec, from Novartis, and Sutent, made by Pfizer Inc.

Bayer HealthCare is a subsidiary of Germany's Bayer AG.



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