FDA Approves ‘Landmark’ Cancer Drug That Extended Patients’ Lives in Trial

The Food and Drug Administration announced Wednesday the approval of a new pancreatic cancer treatment drug that nearly doubles patients’ survival times.

Former GOP Sen. Ben Sasse of Nebraska has seen very positive results using it while it was still in its experimental phase.

The drug, known as Rasonque, “a tablet taken once daily, targets multiple forms of a protein called RAS, a key driver of tumor growth in most patients with pancreatic adenocarcinoma, which arises from cells lining the ducts of the pancreas,” the FDA said in a news release.

Researchers have called it a “landmark” development, The Washington Post reported.

Acting FDA Commissioner Kyle Diamantas said regarding the drug, “Today’s approval provides a critical new option for patients facing an extraordinarily difficult and historically hard-to-treat cancer. It is our fundamental duty to deliver more cures and meaningful treatments to patients as quickly as possible.”

“I am immensely proud of the dedicated FDA scientists whose fast, thorough review and relentless commitment made this groundbreaking milestone a reality,” he added.

The FDA noted, “Approximately 90% to 95% of the 67,000 new cases of pancreatic cancer diagnosed in the United States each year are pancreatic adenocarcinoma, according to the National Cancer Institute. Despite representing roughly 3.2% of all cancer diagnoses, pancreatic adenocarcinoma accounts for a

disproportionately high share of cancer deaths, owing to its typically late detection, aggressive disease course, and historically limited treatment options.”

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The average survival time for those diagnosed with pancreatic adenocarcinoma is 6.7 months for those receiving traditional chemotherapy.

However, patients who took Rasonque had a median survival period of 13.2 months in a trial with 500 adults.

Dr. Angelo de Claro, director of the FDA’s Oncology Center of Excellence, said, “This drug showed unprecedented results in an area of high unmet need.”

“The approval was granted 6.5 months before the user fee deadline, demonstrating the FDA’s commitment to accelerating the approval of new cancer treatments for patients with serious and life-threatening conditions,” he added.

The FDA issued a “safe to proceed” letter in April, allowing patients expanded access to the experimental drug.

The Associated Press reported, “The drug garnered public attention earlier this year when former Sen. Ben Sasse, R-Neb., described on CBS’ ’60 Minutes’ how he has had less pain while taking it. A surge in public interest led the FDA to allow ‘expanded access,’ before the drug’s official approval, for patients who met certain criteria.”

Harsh Singh, the program director of hepatobiliary and pancreas oncology at Mass General Brigham Cancer Institute, told The Washington Post, “This is possibly the biggest advance we have seen in pancreatic cancer, period.”

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