US FDA approves UroGen's bladder cancer drug

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Bengaluru: The U.S. Food and Drug Administration on Thursday approved UroGen Pharma's drug to treat a type of bladder cancer, providing an alternative treatment as opposed to traditional surgical procedures.

U.S.-listed shares of the Israel-based company were up about 50% in afternoon trading.

The approval follows a late-stage trial with 223 patients, in which 78% of the participants showed a complete response, meaning all signs of cancer disappeared in response to the treatment.

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Scotiabank analyst George Farmer called the decision a "major positive outcome," noting that regulators were "moved by the quality of the clinical trial results, despite lack of solid randomized data".

The FDA appreciated the non-surgical treatment option, describing it as "a huge win for patients with recurrent low-grade tumors" as it involves "a simple drug instillation in a doctor's office," Farmer added.

Zusduri is a gel-based formulation that keeps chemotherapy in the bladder for a longer duration, aiming to reduce tumor recurrence and avoid repeated surgeries.

UroGen said it expects the treatment to be available in the U.S. on or around July 1.

Last month, an FDA advisory panel narrowly

opposed

approval of the drug citing concerns that a single arm study for efficacy might not be enough to indicate sustained benefits.

The panel warned that such precedents could be problematic given existing surgical alternatives.

The disease, a type of non-muscle invasive bladder cancer, affects about 82,000 people in the U.S. each year, with around 59,000 experiencing a recurrence, according to UroGen.

Current standard-of-care treatments include surgical procedures such as transurethral resection of bladder tumor, in which doctors insert a thin tube through the urethra to remove the tumor.

News Source:

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