US FDA approves J&J's bladder cancer treatment

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Bengaluru: The U.S. Food and Drug Administration has approved Johnson & Johnson's drug delivery system for patients with a type of bladder cancer, the drugmaker said on Tuesday, offering a potential alternative to surgically remove the organ.

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About 75% of bladder cancer cases are non-muscle-invasive at the time of diagnosis, according to government data.

The approval was based on data from a mid-stage study, in which more than 82% of the patients showed no signs of cancer after three months and over half of them remained cancer-free at least for a year after the treatment with Inlexzo.

"This drug, at ultra low doses for long periods of time... behaves in a way that not only pushes the disease into remission, but then maintains it through some immune memory," Christopher Cutie, vice president and disease area leader for bladder cancer, at J&J, told Reuters ahead of the FDA decision.

Inlexzo, also known as TAR-200, is inserted directly into the bladder where it remains for three weeks per treatment cycle for up to 14 cycles, the company said.

It does not interfere with daily activities and provides sustained release of chemotherapy drug, gemcitabine, into the bladder.

Most common side-effects associated with the treatment include urinary frequency, urinary tract infection and pain or burning sensation during urination, J&J said.

The drug is also being tested in patients with muscle-invasive bladder cancer.

Last year, J&J had discontinued a late-stage study testing TAR-200 in some patients with muscle-invasive bladder cancer after it failed to show superior benefits compared to chemoradiation.

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