



Innovative Therapy Delivers Hope For Patients With Certain Types Of Bladder Cancer

After decades of limited options, a groundbreaking FDA-approved treatment is opening doors for people with certain types of bladder cancer.

Supported by Johnson & Johnson



Bill is a real patient and a volunteer with the SHARE Network, a Johnson & Johnson program made up of people who are dedicated to inspiring others through their personal health journeys and stories of caring. Every patient's experience is unique and Bill's journey is not representative of all patients.

Sia Daneshmand, M.D., Professor of Urology, Director of Urologic Oncology at the Norris Comprehensive Cancer Center, Keck School of Medicine of University of Southern California, provides his expert insights as SunRISe-1 principal investigator and has been compensated by Johnson & Johnson for his time to develop this content.

Approaching retirement after decades of building a successful family-run construction business, Bill looked forward to slowing down and working alongside his son. He was, by all accounts, a healthy and active man, constantly on the move at job sites, climbing ladders, and rarely sitting still. But four words changed everything: “You have bladder cancer.”

The diagnosis came as a shock. Bill had quit smoking years ago, which is a risk factor.¹

Suddenly, Bill was confronting a disease with historically limited treatment options.²

“The problem in bladder cancer is that the tumors keep coming back and we run out of treatment options for the patients,” said Sia Daneshmand, M.D., Professor of Urology, Director of Urologic Oncology at the Norris Comprehensive Cancer Center, Keck School of Medicine of University of Southern California. “Eventually, we’ll recommend radical cystectomy (surgical bladder removal), which is truly a life-altering surgery.”

For Bill, one thing was clear: “From day one, it was my priority to keep my bladder.”

Refusing to settle, and with the support of his family and a willingness to try another treatment option, he enrolled in a clinical trial where investigators were evaluating a groundbreaking approach for certain types of bladder cancer.

Sharing decisions with the care team from the start

Bladder cancer is the sixth most common cancer in the U.S., with an estimated 84,000 new cases diagnosed in 2025. Non-muscle invasive bladder cancer (NMIBC) accounts for 75 percent of new cases and often behaves like a chronic disease, requiring constant surveillance and repeated treatments. Carcinoma in situ (CIS) is found in about 10 percent of NMIBC cases.^{3,4,5}

Bill represents the highest-risk segment of NMIBC patients, those with recurrent, high-grade disease following Bacillus Calmette-Guérin (BCG) treatment who face the greatest likelihood of recurrence and progression. An estimated 2,000 patients represent this segment of NMIBC in the U.S.

At the time, he noticed blood in his urine one day and turned to a longtime client who was a urologist. His urologist suspected a kidney stone. But, when it was removed and tested, Bill learned he had an aggressive form of bladder cancer. At this point, Bill only confided in a few of his close friends and wife, keeping the diagnosis from his children

until he had more answers.

Bill began the standard first-line treatment, BCG therapy—an immunotherapy administered into the bladder that patients have to hold for a few hours.^{6,7} Bill faithfully underwent treatment every Monday.

Historically, however, up to 40 percent of patients become unresponsive to BCG and Bill's experience was no different.⁶ After completing a recommended course of BCG treatment, his cancer persisted. Bill's urologist explained that if BCG didn't work the first time, it likely wouldn't work with additional rounds.

For decades, when BCG therapy has failed, patients faced limited treatment options.⁸ Radical cystectomy is often the recommended next step.⁸ Delaying bladder removal has been associated with worse outcomes in certain patients, including cancer spreading to other parts of the body, which can be life threatening.⁹ This surgery often involves removal of one or more organs and can lead to huge lifestyle changes, including living with a urostomy bag—a small pouch worn outside the body to collect urine after the bladder is removed.⁸

For Bill, the prospect of a bag or major surgery was incompatible with the demands of the work and life he loved.

“I can't work with a bag on me. I'm still climbing ladders and crawling under sinks to visualize problems during bathroom and kitchen remodels,” Bill recalled thinking about bladder removal as an option. “I want no part in living with a urostomy bag, that sounds uncomfortable...I want to fight to preserve my bladder for as long as I possibly can.”

“I wanted a solution that would fit into my life while I was still working and staying active,” Bill said. “That's when my urologist turned me on to Dr. Daneshmand, a urologic oncologist.”

From the start, Bill was determined to be an active participant in every conversation about treatment, asking to see scans and wanting to understand each step. For him, shared decision-making was non-negotiable.

Determined not to have bladder cancer define him, Bill didn't hesitate when Dr. Daneshmand told him about a breakthrough therapy. He saw a clinical trial as a chance to help himself and others facing the same diagnosis.

"I was willing to try an alternative treatment option if it meant the possibility of keeping my bladder," Bill continued. "I thought, maybe what I go through helps the next person down the line, too."

Saying yes to innovative ways

Worried about Bill, his wife finally shared the bladder cancer news with their son Bill Jr. Bill Jr. was devastated to learn of his father's diagnosis but he and his wife, Melissa, immediately jumped in to support Bill, despite their recent move hundreds of miles away to Nevada.

"We never would have left California if this had happened while we were there. I pretty much spent every day with my father for the last 30 years, and I moved away from my best friend," recalled Bill Jr. After learning of his father's diagnosis, "I felt just powerless. ...From that point on, there were no secrets."

Bill brought his family into key discussions with Dr. Daneshmand and his care team.

"We started joining every appointment, calling in, asking questions, and taking notes," Melissa added. "We had our tears. And then it was action time. So, I think that's very important. Otherwise just being sad is not going to get you very far."

As care partners, Melissa and Bill Jr. said it was important to recognize that whatever was happening with his dad wasn't about them. Specifically, they said to remember

it's about your loved one who's sick. Your job is to step up, listen more than you talk, stay alert at doctor's appointments, and help your loved one make healthier changes.

During the trial, a cancer medication was delivered into the bladder through an intravesical drug releasing system (iDRS) called INLEXZO™ (gemcitabine intravesical system). INLEXZO™ is the first and only iDRS to provide prolonged local delivery of a cancer medication into the bladder.¹⁰⁻¹²

INLEXZO™ is approved by the U.S. FDA and indicated for the treatment of adults with a type of cancer of the lining of the bladder called NMIBC, that has not spread to other parts of the body, and that did not respond to treatment with BCG. You should not receive INLEXZO™ if you have any type of tear in your bladder or are allergic to gemcitabine or any of its ingredients.¹⁰

Please see additional Important Safety Information and complete list of ingredients in gemcitabine below.

Daneshmand describes the therapy as an “off-the-shelf” option.

“Insertion is done in an outpatient setting during a brief procedure,” Dr. Daneshmand said. “There’s no need for general anesthesia and patients are awake. INLEXZO remains in the bladder for three weeks per treatment cycle for up to 14 cycles.”

“When INLEXZO was placed into my bladder, it felt similar to a catheterization,” said Bill, something he had experienced routinely.

Reclaiming your story

After 18 months of treatment, Bill got the news he'd hoped for: “I'm never going to forget being told there was no evidence of disease. It was just an incredible relief.” He has been cancer-free for over two years now.

Now, after years of hard work and uncertainty, Bill has finally realized his dream of retirement. He's found a new sense of peace and purpose on the family's ranch in scenic Nevada, where open spaces stretch for miles. Days begin and end with ranch life: where Bill is surrounded by the animals he loves – horses, mountain goats, and Australian cattle dogs.

While Melissa cares for the animals like children, Bill loves pitching in. Most days he works with his son managing rental properties, a return to a partnership they adore. Bill keeps his regular check-up appointments with Dr. Daneshmand.

“This field has not seen significant change in the way certain types of bladder cancer have been treated in over 40 years,” said Dr. Daneshmand. “INLEXZO is changing the way we treat patients like Bill who haven't responded to traditional BCG therapy.”

“A cancer diagnosis doesn't have to be the end of your story,” said Bill. He also stresses the importance of shared clinical decision-making and insisting on transparency with your care team. Above all, Bill emphasizes the importance of family support. “Let people help you. Bill Jr. and Melissa were with me every step, and that made all the difference.”

“Was it worth going through all this treatment? Absolutely. I still have my bladder, and that is one of the most important things to me,” Bill said. “I hope my story encourages others to fight for the life they want and deserve—and to know options are out there.”

Dr. Daneshmand added, “Stories like Bill's are why we do this work. The goal is for patients to not only feel empowered in their treatment decisions, but to also feel a sense of hope.”

LEARN MORE

Johnson & Johnson

What is INLEXZO™?

INLEXZO™ (gemcitabine intravesical system) is a prescription medicine for the treatment of adults with a type of cancer of the lining of the bladder called non-muscle invasive bladder cancer (NMIBC), that has not spread to other parts of the body, and that did not respond to treatment with Bacillus Calmette-Guérin (BCG).

IMPORTANT SAFETY INFORMATION

Do not receive INLEXZO™ if you:

- have a tear or hole (perforation) of your bladder.
- have had an allergic reaction to gemcitabine or any of the ingredients in INLEXZO™.

See the end of this Patient Information for a complete list of ingredients in INLEXZO™.

Before receiving INLEXZO™, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant, or plan to become pregnant. INLEXZO™ can harm your unborn baby. You should not become pregnant during treatment with INLEXZO™. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with INLEXZO™.

Females who are able to become pregnant:

- Your healthcare provider will check to see if you are pregnant before starting treatment with INLEXZO™.
- Use effective birth control (contraception) during treatment with INLEXZO™ and for 6 months after final removal of INLEXZO™.

Males treated with INLEXZO™:

- If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with INLEXZO™ and for 3 months after final removal of INLEXZO™.
- are breastfeeding, or plan to breastfeed. It is not known if INLEXZO™ passes into your breastmilk. Do not breastfeed during treatment with INLEXZO™ and for 1 week after final removal of INLEXZO™.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive INLEXZO™?

- INLEXZO™ will be inserted and removed by your healthcare provider.
- INLEXZO™ is inserted into your bladder through a tube called a urinary catheter 1 time every 3 weeks for up to 6 months (8 doses) and then 1 time every 12 weeks for up to 18 months (6 doses).
- INLEXZO™ is removed after 3 weeks of being inserted (3-week indwelling period).
- Your healthcare provider will decide how many INLEXZO™ treatments you will receive.
- Your healthcare provider may give you antibiotics before INLEXZO™ is inserted or removed.
- It is very important that you go to all of your appointments. If you miss any appointments, call your healthcare provider as soon as possible to schedule your appointment.

Before receiving INLEXZO™:

- Do not empty your bladder right before your procedure to insert INLEXZO™.

After receiving INLEXZO™:

- Drink about 6 to 7 cups (1500 mL) of fluids per day during treatment with INLEXZO™ to make sure you produce enough urine for the medicine to be released into the bladder.

- You can urinate normally. There is no need to hold your urine.
- Avoid contact between your skin and urine.
- To urinate, **males and females** should sit on the toilet and flush after each use.
- Wash your hands with soap and water and wash your genital area with water after each time you urinate.
- Wash clothing soiled with urine right away and separately from other clothing.

After your healthcare provider removes INLEXZO™:

Avoid contact between your skin and urine for at least 24 hours after INLEXZO™ is removed.

What should I avoid after INLEXZO™ is inserted?

Tell your healthcare provider that you have INLEXZO™ before having a type of scan called Magnetic Resonance Imaging (MRI).

INLEXZO™ may be used under specific conditions. Your healthcare provider will give you an MRI Safety Information Card. Keep the card in a safe place and show it to all of your healthcare providers. The card contains important information in case you need to have an MRI. Your healthcare provider will review the information on the MRI Safety Information Card and determine the conditions they can safely do an MRI scan while INLEXZO™ is in your bladder.

What are the possible side effects of INLEXZO™?

The most common side effects of INLEXZO™ include:

- frequent need to pass urine more often than usual
- urinary tract infection
- pain or burning sensation when passing urine
- urgent need to pass urine
- decreased hemoglobin
- decreased lymphocytes
- blood in urine
- increased creatinine
- increased potassium
- increased aspartate aminotransferase
- decreased sodium

- increased lipase
- pain in the urinary tract (felt in the lower stomach area or lower back)
- bladder irritation
- increased alanine transaminase

INLEXZO™ may cause fertility problems in males, which may affect your ability to have children. It is unknown if these side effects of fertility are reversible. Talk to your healthcare provider if this is a problem for you.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of INLEXZO™.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What are the ingredients in INLEXZO™?

Active ingredient: gemcitabine hydrochloride

Inactive ingredients for gemcitabine component: polyethylene glycol 8000, povidone K30, and urea.

Inactive ingredients for osmotic components: FD&C Blue No.1, polyethylene oxide 600,000, and urea.

Please read full Prescribing Information for INLEXZO™.

cp-520100v1

References

1. American Cancer Society. Bladder cancer causes, risk factors, and prevention. Accessed August 20, 2025. <https://www.cancer.org/cancer/types/bladder-cancer/causes-risks-prevention.html>

2. Jiang S, Redelman-Sidi G. BCG in bladder cancer immunotherapy. *Cancers (Basel)*. 2022;14(13):3073. doi:10.3390/cancers14133073
3. Grabe-Heyne K, Henne C, Mariappan P, et al. Intermediate and high-risk non-muscle-invasive bladder cancer: an overview of epidemiology, burden, and unmet needs. *Front Oncol*. 2023;13:1170124. doi:10.3389/fonc.2023.1170124
4. American Cancer Society. Cancer facts & figures 2025. Accessed August 20, 2025. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acf.pdf>
5. Llano A, Chan A, Kuk C, et al. Carcinoma In Situ (CIS): Carcinoma in situ (CIS): is there a difference in efficacy between various BCG strains? A comprehensive review of the literature. *Cancers (Basel)*. 2024;16(2):245. doi:10.3390/cancers16020245
6. Böhle A, Jocham D, Bock PR. Intravesical Bacillus Calmette-Guérin versus mitomycin C for superficial bladder cancer: a formal meta-analysis of comparative studies on recurrence and toxicity. *J Urol*. 2003;169(1):90-95. doi:10.1016/S00225347(05)64043-8
7. American Cancer Society. Treating bladder cancer. Accessed August 20, 2025. <https://www.cancer.org/cancer/types/bladder-cancer/treating/by-stage.html>
8. Aminoltejari K, Black PC. Radical cystectomy: a review of techniques, developments and controversies. *Transl Androl Urol*. 2020;9(6):3073-3081. doi:10.21037/tau.2020.03.23
9. Taylor J, Kamat A, et al. Long-term outcomes of bladder-sparing therapy vs radical cystectomy in BCG-unresponsive non-muscle-invasive bladder cancer. *BJU Int*. 2025;135(2):260-268
10. INLEXZO™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.
11. Palugan L, Cerea M, Cirilli M, et al. Intravesical drug delivery approaches for improved therapy of urinary bladder diseases. *Int J Pharm X*. 2021;3:100100. doi:10.1016/j.ijpx.2021.100100
12. Data on file. Janssen Biotech, Inc.

© Johnson & Johnson and its affiliates 2026 04/26 cp-524909v2

The news and editorial staffs of The New York Times had no role in this post's creation.