

## ROYALTY PHARMA AND FERRING PHARMACEUTICALS ENTER INTO US \$500 MILLION ROYALTY AGREEMENT FOR NEW INTRAVESICAL GENE THERAPY ADSTILADRIN® (NADOFARAGENE FIRADENOVEC-VNCG)

- Royalty Pharma to pay Ferring \$300 million upfront and a potential \$200 million milestone payment in exchange for royalties on the sales of Ferring’s intravesical gene therapy Adstiladrin® (nadofaragene firadenovec-vnvg)
- Transaction provides Ferring with significant non-dilutive capital to support the manufacturing capacity expansion, commercialization and further clinical development of Adstiladrin for bladder cancer patients in the United States

**NEW YORK, NY, and SAINT PREX, SWITZERLAND, August 24, 2023** - Royalty Pharma plc (Nasdaq: RPRX) and Ferring Pharmaceuticals today announced that Royalty Pharma has acquired a synthetic royalty on US net sales of Ferring’s Adstiladrin® (nadofaragene firadenovec-vnvg) for up to US \$500 million comprised of an upfront payment of US \$300 million and a US \$200 million milestone payment. The milestone payment is contingent on certain manufacturing goals that are expected to be achieved in 2025 for the FDA-approved intravesical gene therapy that Ferring will make available next month through an early experience program for the treatment of adult patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Under the terms of the agreement, Royalty Pharma is acquiring a 5.1% percentage royalty on net sales of Adstiladrin in the United States, which will increase to 8.0% upon payment of the manufacturing-related milestone. The royalty is expected to end in the early to mid-2030s.

“This major investment by Royalty Pharma, the largest buyer of biopharmaceutical royalties and a leading funder of innovation, is yet another demonstration of the value and confidence in our gene therapy Adstiladrin to address significant unmet medical needs for patients. It also highlights its significant potential as a key growth driver for Ferring, and our commitment to Uro-Oncology,” said Jean-Frédéric Paulsen, Executive Chairman of Ferring Pharmaceuticals.

Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 75% of all new bladder cancer cases.<sup>i</sup> Adstiladrin is a non-replicating adenovirus vector-based gene therapy for the treatment of adult patients with high-risk BCG-unresponsive NMIBC. Although BCG remains the first-line standard of care for people living with high-grade NMIBC, more than 50% of patients who receive initial treatment with BCG will experience disease recurrence and progression within one year, with many developing BCG-unresponsive disease.<sup>ii</sup> In April 2023, the FDA approved a Prior-Approval Supplement (PAS) to the Biologics License Application (BLA) for the therapy which enabled the scale-up of drug substance manufacturing process.

“After several decades of little progress in the field, Adstiladrin brings a major innovation to patients with high-risk NMIBC who no longer respond to current first-line treatment and have few other good options. Our ambition is for Adstiladrin to become the new standard of care and the backbone therapy

for these patients and to drive research in other urothelial cancers. This agreement positions us well for continued significant and sustained investment to further advance Adstiladrin as the foundation of our leadership drive in Uro-Oncology,” said Bipin Dalmia, Global Head, Uro-Oncology Franchise of Ferring Pharmaceuticals.

“We are delighted to partner with Ferring, a research-driven, global specialty biopharmaceutical company. This investment is consistent with our strategy of acquiring royalties on innovative therapies in areas of high unmet patient need,” said Pablo Legorreta, founder and Chief Executive Officer of Royalty Pharma. “Adstiladrin is the first gene therapy in our diversified royalty portfolio. We believe it has blockbuster potential and we are pleased to provide funding to support the launch of Adstiladrin and help Ferring reach as many patients as possible with this important therapy in the United States.”

## About Adstiladrin

Adstiladrin® (nadofaragene firadenovec-vncg) is a gene therapy developed as a treatment for adult patients with BCG-unresponsive NMIBC. It is a non-replicating adenovirus vector-based gene therapy containing the gene encoding interferon alfa-2b protein, administered by catheter into the bladder once every three months. The vector enters the cells of the bladder wall, releasing the interferon gene. The internal cell machinery translates the interferon DNA sequence, resulting in the cells secreting high quantities of interferon alfa-2b protein, a recombinant analog of the naturally occurring protein the body uses to fight cancer. This novel gene therapy approach thereby turns the patient’s own bladder wall cells into interferon microfactories, enhancing the body’s natural defenses against the cancer. Nadofaragene firadenovec-vncg has been studied in a clinical trial program that includes 157 patients with high-grade, BCG-unresponsive NMIBC who had been treated with adequate BCG previously and did not see benefit from additional BCG treatment (full inclusion criteria published on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02773849): NCT02773849).

US FDA approval of Adstiladrin on December 16, 2022 was based on results of the Phase 3 clinical trial, which met its primary endpoint with more than half (51%, n=50 of 98; 95% CI 41 to 61) of patients with carcinoma in situ with or without concomitant high-grade Ta or T1 disease (CIS ± Ta/T1) achieving a complete response (CR) by three months. Of the patients who achieved an initial CR, 46% (n=23 of 50) continued to remain free of high-grade recurrence at 12 months.

## INDICATION

Adstiladrin is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

## IMPORTANT SAFETY INFORMATION

**CONTRAINDICATIONS:** Adstiladrin is contraindicated in patients with hypersensitivity to interferon alfa or any component of the product.

## WARNINGS AND PRECAUTIONS:

- *Risk with delayed cystectomy: Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after 3 months or if CIS recurs, consider cystectomy.*

- *Risk of disseminated adenovirus infection: Persons who are immunocompromised or immunodeficient may be at risk for disseminated infection from ADSTILADRIN due to low levels of replication-competent adenovirus. Avoid ADSTILADRIN exposure to immunocompromised or immunodeficient individuals.*

**DOSAGE AND ADMINISTRATION:** Administer Adstiladrin by intravesical instillation only. Adstiladrin is not for intravenous use, topical use, or oral administration.

**USE IN SPECIFIC POPULATIONS:** Advise females of reproductive potential to use effective contraception during Adstiladrin treatment and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during Adstiladrin treatment and for 3 months after the last dose.

**ADVERSE REACTIONS:** The most common (>10%) adverse reactions, including laboratory abnormalities (>15%), were glucose increased, instillation site discharge, triglycerides increased, fatigue, bladder spasm, micturition (urination urgency), creatinine increased, hematuria (blood in urine), phosphate decreased, chills, pyrexia (fever), and dysuria (painful urination).

**You are encouraged to report negative side effects of prescription drugs to FDA.** Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-332-1088. You may also contact Ferring Pharmaceuticals at 1-888-FERRING.

## About Royalty Pharma plc

Founded in 1996, Royalty Pharma is the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the biopharmaceutical industry, collaborating with innovators from academic institutions, research hospitals and non-profits through small and mid-cap biotechnology companies to leading global pharmaceutical companies. Royalty Pharma has assembled a portfolio of royalties which entitles it to payments based directly on the top-line sales of many of the industry's leading therapies. Royalty Pharma funds innovation in the biopharmaceutical industry both directly and indirectly - directly when it partners with companies to co-fund late-stage clinical trials and new product launches in exchange for future royalties, and indirectly when it acquires existing royalties from the original innovators. Royalty Pharma's current portfolio includes royalties on more than 35 commercial products, including Vertex's Trikafta, Kalydeco, Orkambi and Symdeko, Biogen's Tysabri, AbbVie and Johnson & Johnson's Imbruvica, Astellas and Pfizer's Xtandi, GSK's Trelegy, Novartis' Promacta, Pfizer's Nurtec ODT, Johnson & Johnson's Tremfya, Roche's Evrysdi, Gilead's Trodelvy, and 11 development-stage product candidates.

## About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. Headquartered in Saint-Prex, Switzerland, Ferring is a leader in reproductive medicine and women's health, and in specialty areas within gastroenterology and urology. Ferring has been developing treatments for mothers and babies for over 50 years and has a portfolio covering treatments from conception to birth. Founded in 1950, privately-owned Ferring now employs around 7,000 people worldwide, has its own operating subsidiaries in more than 50 countries and markets its products in 100 countries.

Learn more at [www.ferring.com](http://www.ferring.com), or connect with us on Twitter, Facebook, Instagram, LinkedIn and YouTube.

## Advisors

Goodwin Procter LLP and Fenwick & West LLP acted as legal advisors to Royalty Pharma. Orrick, Herrington & Sutcliffe LLP acted as legal advisor to Ferring.

## Royalty Pharma Forward-Looking Statements

The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This document contains statements that constitute “forward-looking statements” as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the company’s opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of Royalty Pharma’s strategies, financing plans, growth opportunities and market growth. In some cases, you can identify such forward-looking statements by terminology such as “anticipate,” “intend,” “believe,” “estimate,” “plan,” “seek,” “project,” “expect,” “may,” “will,” “would,” “could” or “should,” the negative of these terms or similar expressions. Forward-looking statements are based on management’s current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of Royalty Pharma’s performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, and other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of the company’s control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this document are made only as of the date hereof. The company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law.

Certain information contained in this document relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the company's own internal estimates and research. While the company believes these third-party sources to be reliable as of the date of this document, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this document involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while the company believes its own internal research is reliable, such research has not been verified by any independent source.

For further information, please reference Royalty Pharma's reports and documents filed with the U.S. Securities and Exchange Commission (SEC). You may get these documents by visiting EDGAR on the SEC website at [www.sec.gov](http://www.sec.gov).

## References

<sup>i</sup>European Association of Urology. Guidelines for non-muscle-invasive bladder cancer (TaT1 and CIS). Available at <https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer>

<sup>ii</sup>Boorjian SA, Alemozaffar M, Konety BR, et al. Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial. *Lancet Oncol* 2021; 22:107–17.

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