



Xeris Announces Orange Book Listing of U.S. Patent for Recorlev®

August 25, 2025

Recorlev now holds four Orange Book-listed patents to 2040

CHICAGO--(BUSINESS WIRE)--Aug. 25, 2025-- Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a fast-growing biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies, today announced the U.S. Patent and Trademark Office has issued patent number 12,377,096 to the Company for Recorlev® (levoketoconazole) and that this patent is now listed in the publication, "Approved Drug Products with Therapeutics Equivalence Evaluations," commonly known as the "Orange Book." This patent, entitled "Methods of Treating Disease with Levoketoconazole," covers therapeutic uses of levoketoconazole in methods that minimize drug-drug interactions between levoketoconazole and other commonly co-administered drugs known as MATE1 substrates, and extends to March 2040.

"We are pleased to expand and further strengthen the intellectual property protection for Recorlev with the grant of our latest patent and its addition to the FDA's Orange Book," said John Shannon, Chief Executive Officer of Xeris. "Recorlev represents a meaningful therapeutic advancement for patients with endogenous Cushing's syndrome and hypercortisolemia, a complex and underserved condition. As we continue to make strategic investments in education, patient support, and market access, we are equally committed to protecting the long-term value of this important asset. Strengthening our IP position reinforces our confidence in Recorlev's growth potential and our mission to improve the lives of patients with rare endocrine diseases."

Orange Book-listed patents cover drugs that the FDA has approved and deemed both safe and effective for the general public's use. Inclusion in the book's list of patents can make it easier for drug makers to monitor for new generic drugs that could potentially arrive on the U.S. market and infringe on their patents.

Recorlev® (levoketoconazole) was approved by the FDA in December 2021 for the treatment of endogenous Cushing's syndrome in adult patients for whom surgery is not an option or has not been curative. Recorlev is an adrenal steroidogenesis inhibitor and a purified enantiomer of ketoconazole. The product is protected by multiple patents listed in the FDA's Orange Book. Recorlev is not classified as a controlled substance by the U.S. Drug Enforcement Administration (DEA).

Important Safety Information

- RECORLEV is contraindicated in patients:
 - With cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT >3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug-induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease
 - Taking drugs that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes
 - With prolonged QTcF interval >470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome
 - With hypersensitivity to levoketoconazole, ketoconazole, or any excipient in RECORLEV
 - Taking certain drugs that are sensitive substrates of CYP3A4 or CYP3A4 and P-gp
- RECORLEV may lead to hypocortisolism with a potential for life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary
- Hypersensitivity to RECORLEV has been reported. Anaphylaxis has been reported with oral ketoconazole
- RECORLEV may lower serum testosterone in men and women. Inform patients to report associated symptoms
- Most common adverse reactions are nausea/vomiting, hypokalemia, hemorrhage/contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema
- Avoid use of strong CYP3A4 inhibitors and inducers 2 weeks before and during RECORLEV treatment. Consult approved product labeling for drugs that are substrates of CYP3A4, P-gp, OCT2, and MATE prior to initiating RECORLEV. For atorvastatin, metformin, and gastric acid modulators, see full Prescribing Information for recommendations regarding concomitant use with RECORLEV
- Breastfeeding is not recommended during treatment and for one day after final dose

Please see [Medication Guide](#) and full [Prescribing Information](#), including Boxed Warning, for RECORLEV.

About Xeris

Xeris (Nasdaq: XERS) is a fast-growing biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products: Recorlev®, for the treatment of endogenous Cushing's syndrome; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, and a gastrointestinal motility inhibitor when used as a diagnostic aid; and Keveyis®, a proven therapy for primary periodic paralysis. Xeris also has a pipeline of development programs led by

XP-8121, a Phase 3-ready, once-weekly subcutaneous injection for hypothyroidism, as well as early-stage programs leveraging Xeris' technology platforms, XeriSol® and XeriJect®, for its partners.

Xeris Biopharma Holdings is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on [X](#), [LinkedIn](#), or [Instagram](#).

Forward-Looking Statements

Any statements in this press release other than statements of historical fact are forward-looking statements. Forward-looking statements include, but are not limited to, statements about future expectations, plans, opportunities, and prospects for Xeris Biopharma Holdings, Inc., including statements regarding its strategic investments in education, patient support, and market access, commitment to protecting the long-term value of its assets, the growth potential of its drug products, including Recorlev, the market and therapeutic potential of its products and product candidates, and other statements containing the words "will," "would," "continue," "expect," "should," "anticipate," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris' experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, geopolitical factors and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The various factors that could cause Xeris' actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements, include, but are not limited to, its financial position and need for financing, including to fund its product development programs or commercialization efforts, whether its products will achieve and maintain market acceptance in a competitive business environment, its reliance on third-party suppliers, including single-source suppliers, its reliance on third parties to conduct clinical trials, the ability of its product candidates to compete successfully with existing and new drugs, and its collaborators' ability to protect its intellectual property and proprietary technology, and general macroeconomic and geopolitical conditions, including the possibility of an economic downturn, changes in governmental priorities and resources, announced or implemented tariffs, and market volatility. No assurance can be given that such expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional risks and information about potential impacts of financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect Xeris can be found in Xeris' filings, including its most recently filed Annual Report on Form 10-K and subsequent filings with the U.S. Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Forward-looking statements in this communication are based on information available to management, as of the date of this communication and, while the Company believes its assumptions are reasonable, actual results may differ materially. Subject to any obligations under applicable law, the Company does not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

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