# Xeris Hosts Webinar Detailing Its Comprehensive Development Program for XP-8121, an Investigational, Once-Weekly Subcutaneous Levothyroxine for Hypothyroidism

September 9, 2026

*Initiation of Phase 3 registrational study on track by year-end; topline results expected in late 2028; U.S. FDA approval and launch anticipated in 2030*

*The Company expects XP-8121 peak net revenue potential of $1 to $3 billion*

CHICAGO--(BUSINESS WIRE)--Sep. 9, 2026-- 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, will host an XP-8121 Program Overview today at 10 a.m. ET detailing a comprehensive clinical development strategy, including Cornerstone, its Phase 3 registrational study design, as well as the commercial opportunity for XP-8121, its investigational once-weekly subcutaneous levothyroxine formulation for the treatment of hypothyroidism.

"We are excited to showcase our comprehensive development program for XP-8121 and highlight why we have a high level of confidence in its success," said John Shannon, Chairman and Chief Executive Officer, Xeris. "With a well-established unmet need, and a differentiated product profile, we believe that XP-8121 could reach $1 to $3 billion in peak net revenue, cementing Xeris as a leading biopharmaceutical company. And most importantly, if approved, XP-8121 has the potential to redefine care and improve the lives of millions of patients."

**XP-8121's Comprehensive Evidence Generation Program**

**Cornerstone — Phase 3 Registrational Study**

- **Objective**: To demonstrate that once-weekly subcutaneous XP-8121 is therapeutically equivalent to daily oral levothyroxine in patients with well-controlled hypothyroidism, as required by the U. S. Food and Drug Administration (FDA) for approval.
- **Design**: Randomized 1:1 controlled study; participants receive subcutaneous XP-8121 or oral levothyroxine for 54 weeks, with treatment assessments and laboratory evaluations conducted every six weeks throughout the study.
- **Enrollment**: 500 adults and adolescents with well-controlled hypothyroidism across more than 50 U. S. clinical trial sites, representing both community and academic settings.
- **Primary endpoint**: Proportion of subjects with thyroid-stimulating hormone (TSH) within the normal range at both weeks 48 and 54.
- **Key secondary endpoints**: Proportion of time TSH and Free T4 are each within normal range during the final 30 weeks of the study; supportive pharmacokinetic (PK) and PK/pharmacodynamic (PD) endpoints designed to quantify the clinical advantages of once-weekly subcutaneous delivery.
- **Statistical design**: 15% non-inferiority margin; greater than 90% power; informed by feedback from the FDA on endpoints and statistical powering.

**Capstone — Pediatric Study**

- **Objective**: To confirm appropriate dosing and evaluate safety of XP-8121 in pediatric patients, extending the evidence base across all age groups.

**Touchstone — Special Population Study**

- **Objective**: To evaluate XP-8121 in patients with inconsistent thyroid control despite maximal oral therapy.

**Real-world evidence**

- **Objective**: To quantify the burden and consequences of inadequate thyroid control through ongoing analyses of claims and real-world datasets conducted in collaboration with leading experts in the field.

**Clinical Perspective**

In addition to Company representatives, key opinion leader and Cornerstone investigator Dr. David Robertson, a leading endocrinologist at Atlanta Diabetes Associates and Piedmont Hospital Atlanta with nearly three decades of experience treating complex thyroid and metabolic conditions, will participate in today's program overview.

"As an endocrinologist and clinical investigator, I see firsthand the challenges that persist for patients who cannot achieve TSH normalization on existing oral therapies," said Dr. David Robertson. "Despite our best efforts, a meaningful subset of patients faces a frustrating cycle of dose escalations, repeated testing, and persistent symptoms, driven by factors such as unreliable GI absorption, drug interactions, and comorbid conditions. For the first time in decades, XP-8121 offers a fundamentally different approach to levothyroxine delivery. It has the potential to help difficult-to-treat patients achieve biochemical control and reach their treatment goals. The Phase 1 and Phase 2 data provide meaningful foundation around its safety profile and dose-conversion results, and I look forward to serving as an investigator in the Cornerstone study to help in the process towards generating additional data and potentially bringing a new option closer to the patients who need it most."

**How to Register and Access the Event**
The XP-8121 Program Overview webinar will be held **today, Wednesday, September 9, at 10 a.m. ET**.

For registration and access, please click here. A replay of the event, along with the related presentation materials, will also be made available on the "Events and Presentations" section of the Company's Investor Relations website following the live presentation.

**About Hypothyroidism**
Hypothyroidism affects approximately 20 million Americans, the majority of whom are managed with daily oral levothyroxine. Despite treatment, an estimated 3 to 5 million patients fail to achieve adequate biochemical control, largely due to gastrointestinal absorption variability associated with oral administration. Uncontrolled hypothyroidism is associated with meaningful clinical consequences, including cardiovascular disease and increased mortality.

**About XP-8121**
XP-8121 is a Phase 3-ready, once-weekly subcutaneous injection in development for the treatment of hypothyroidism. The program is designed to address persistent challenges associated with existing thyroid hormone replacement therapy and has the potential to provide a differentiated treatment option for people living with hypothyroidism and physicians.

**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 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 multiple early-stage programs leveraging Xeris' technology platforms, XeriSol ® and XeriJect®, for its partners.

Xeris Biopharma Holdings is headquartered in Chicago, IL.

**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 the Company, including among other things, statement regarding the Company's comprehensive clinical development program for XP-8121, the design, objectives, endpoints, enrollment, timing, conduct and expected results of the Cornerstone, Capstone, and Touchstone studies, the ability of XP-8121 to demonstrate therapeutic equivalence of daily oral levothyroxine, achieve applicable clinical endpoints and support regulatory approval, the expected initiation of Cornerstone by year-end 2026, the expected initiation of Touchstone in 2027 and completion of Touchstone in time for inclusion in the Company's New Drug Application submission, and the expected timing of topline results in late 2028, the timing and likelihood of regulatory approval and commercialization of XP-8121, including potential FDA approval and commercial launch in 2030, the market and therapeutic and commercial potential of its products and product candidates, including its expectations regarding the potential of XP-8121 to provide biochemical control, improve patient outcomes and redefine care, and its estimated peak net revenue or sales potential of $1 billion to $3 billion, the timing, duration, and expected results of clinical trials, the timing and expected regulatory approval of its product candidates, the potential utility of its formulation platforms, the advancement of its pipeline, and other statements containing the words "achieve," "anticipate," "believe," "continue," "expect," "estimate," "potential," "should," "will," "would," 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 (including revenue and sales in the near- and long-term), performance or achievements, industry results, market opportunity 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 risk that clinical trials may not be initiated, enrolled, or completed on anticipated timelines, or at all, the risk that results of earlier clinical trials may not be predictive of the results of later-stage clinical trials or may not support regulatory approval, the possibility that the FDA may disagree with the design or conduct of the Company's clinical trials or require additional clinical trials or data, the ability of its product candidates to compete successfully with existing and new drugs, its and collaborators' ability to protect its intellectual property and proprietary technology, the accuracy and completeness of its assumptions and its ability to accurately estimate future financial results and market opportunities, and general macroeconomic and geopolitical conditions, including the possibility of an economic downturn, political unrest, trade disputes, changes in U.S. governmental priorities and resources, announced or implemented tariffs or export controls 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. The risks described herein and in Xeris' U.S. Securities and Exchange Commission filings are not the only risks the Company faces. Additional risks and uncertainties not currently known to it or that it currently deems immaterial may also impact its business operations or financial results. 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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