Faeth Therapeutics Announces Clinical Trial Collaboration and Supply Agreement with Roche to Evaluate PIKTOR in Combination with a Selective Estrogen Receptor Degrader in HR+/HER2- Advanced Breast Cancer

November 16, 2026

Faeth will sponsor and conduct a Phase 1b/2 study evaluating PIKTOR, its investigational all-oral combination of serabelisib and sapanisertib, in combination with the investigational medicine giredestrant

Faeth retains all rights to PIKTOR; under the agreement, Roche will supply giredestrant for use in the study

AUSTIN, Texas--(BUSINESS WIRE)--Nov. 16, 2026-- Faeth Therapeutics (Nasdaq: FTH), a clinical-stage oncology company developing multi-node therapies for cancer patients, including its lead program PIKTOR, today announced that it has entered into a clinical trial collaboration and supply agreement with F. Hoffmann-La Roche Ltd (Roche) to evaluate PIKTOR in combination with the investigational medicine giredestrant in patients with hormone receptor-positive, HER2-negative (HR+/HER2-) advanced breast cancer.

Under the terms of the agreement, Faeth will sponsor and conduct the Phase 1b/2 study (Study FTH-PIK-101), and Roche will supply giredestrant for use in the study. Activation of the PI3K/AKT/mTOR pathway is a recognized mechanism of resistance to endocrine therapy in HR+/HER2- breast cancer, providing the rationale for evaluating PIKTOR in combination with endocrine-directed agents.

“Endocrine therapy remains the backbone of treatment in HR+/HER2- breast cancer, and resistance driven by the PI3K/AKT/mTOR pathway is one of the central problems in this setting,” said Anand Parikh, Chief Executive Officer of Faeth Therapeutics. “We believe PIKTOR’s multi-node approach to this pathway is well suited to patients whose disease has progressed on prior endocrine therapy, and this study will allow us to evaluate that approach in combination with giredestrant and potentially CDK4/6 regimens.”

About PIKTOR

PIKTOR is an investigational, proprietary, all-oral combination of serabelisib, a selective PI3K-alpha inhibitor, and sapanisertib, an mTORC1/mTORC2 inhibitor, designed to inhibit multiple nodes of the PI3K/AKT/mTOR pathway. According to published literature, this pathway is dysregulated in up to 50% of all solid tumors, making it one of the most prevalent therapeutic targets in oncology. PIKTOR is being evaluated in a Phase 2 trial in second-line advanced endometrial cancer (Study FTH-PIK-201), for which Faeth reported preliminary topline results on November 9, 2026. PIKTOR is also being evaluated in a Phase 1b/2 trial in HR+/HER2- advanced breast cancer (Study FTH-PIK-101), in which the first patient was dosed in April 2026 and interim data is anticipated in 2027.

About Faeth Therapeutics

Faeth Therapeutics, Inc. (Nasdaq: FTH) is a clinical-stage biotechnology company focused on improving outcomes for cancer patients through multi-node inhibition of critical oncogenic pathways. The Company’s lead program is PIKTOR, an investigational all-oral combination of serabelisib and sapanisertib in development for endometrial and breast cancer. Faeth was co-founded in 2019 by Anand Parikh and Oliver Maddocks, Ph.D., together with scientific founders Lewis Cantley, Ph.D., the discoverer of the PI3K pathway; Siddhartha Mukherjee, M.D., D.Phil.; Karen Vousden, Ph.D.; Scott Lowe, Ph.D.; and Greg Hannon, Ph.D. For more information, please visit www.faeththerapeutics.com and follow the Company on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the federal securities laws, including the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts and may be identified by words such as “anticipate,” “believe,” “expect,” “intend,” “plan,” “may,” “will,” “would,” “could,” “should,” “estimate,” “potential,” “target,” “on track” and similar expressions, although not all forward-looking statements contain these words. These statements include, but are not limited to, statements regarding: the clinical trial collaboration and supply agreement with Roche and the anticipated benefits thereof; the planned study of PIKTOR in combination with giredestrant, including its design and conduct; the supply of giredestrant for the study; the Company’s expectations regarding its pipeline and development plans, including the Phase 2 trial of PIKTOR in advanced endometrial cancer and the Phase 1b/2 trial of PIKTOR in HR+/HER2- advanced breast cancer and the anticipated timing of interim data; and the potential therapeutic benefits, tolerability profile and differentiation of PIKTOR.

Forward-looking statements are based on management’s current expectations and assumptions and are subject to a number of risks and uncertainties, many of which are beyond the Company’s control, that could cause actual results to differ materially from those expressed or implied. These risks and uncertainties include, among others, risks related to clinical development and the

conduct, timing and results of clinical trials; risks related to reliance on third parties for the supply of investigational agents used in combination studies; the Company's need for additional financing; its limited operating history and history of operating losses; the Company's ability to satisfy applicable Nasdaq listing requirements and to maintain the listing of its common stock; and the other risks and uncertainties described under the headings "Risk Factors" and "Summary of Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 30, 2026, its Quarterly Report on Form 10-Q filed with the SEC on November 3, 2026, and its definitive proxy statement filed with the SEC on April 27, 2026, as well as in the Company's subsequent filings. Forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to update any forward-looking statement, except as required by law.

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