Faeth Therapeutics Announces FDA Grant of Fast Track Designation for PIKTOR Plus Paclitaxel in Biomarker-Selected Advanced Endometrial Cancer

August 17, 2026

— Fast Track designation applies to sapanisertib and serabelisib (PIKTOR) in combination with paclitaxel for the treatment of patients with advanced or recurrent endometrial cancer whose tumors harbor a PI3K/AKT/mTOR pathway alteration

— Faeth expects topline data from its ongoing Phase 2 trial in second-line advanced endometrial cancer (Study FTH-PIK-201) by year-end 2026

AUSTIN, Texas--(BUSINESS WIRE)--Aug. 17, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the combination of sapanisertib and serabelisib (PIKTOR) with paclitaxel for the treatment of patients with advanced or recurrent endometrial cancer whose tumors harbor a PI3K/AKT/mTOR pathway alteration and who have previously been treated with platinum-based chemotherapy and an immune checkpoint inhibitor (ICI).

"Fast Track designation for PIKTOR reflects the significant unmet need in advanced endometrial cancer for patients whose disease has progressed despite platinum-based chemotherapy and an immune checkpoint inhibitor," said Anand Parikh, Chief Executive Officer of Faeth Therapeutics. "We believe PIKTOR's multi-node approach to the PI3K/AKT/mTOR pathway is well suited to this population as our preclinical data suggests that PIKTOR can resensitize patients to chemotherapy."

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), with topline data anticipated by year-end 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 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 change of the Company's corporate name to Faeth Therapeutics, Inc.; the expected commencement of trading of the Company's common stock under the new name and ticker symbol "FTH" and the timing thereof; the Company's expectations regarding its pipeline and development plans, including the Phase 2 trial of PIKTOR in advanced endometrial cancer and the anticipated timing of topline data, and the Phase 1b/2 trial of PIKTOR in HR+/HER2- advanced breast cancer and the anticipated timing of interim data; the potential therapeutic benefits, tolerability profile and differentiation of PIKTOR; the anticipated benefits of Fast Track Designation; and the Company's expectations regarding its cash runway.

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; the Company's need for additional financing; its limited operating history and history of operating losses; risks related to the integration of Faeth; 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 May 15, 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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