Faeth Reports Positive Preliminary Phase 2 Topline Results from the PIK-201 Trial Evaluating PIKTOR in Combination with Paclitaxel in Patients with Advanced Endometrial Cancer

November 9, 2026

- *Confirmed Objective Response Rate (ORR) of 33% in efficacy-evaluable patients (12 of 36), and a disease control rate (DCR) of 83%*
- *Among patients with a PIK3CA mutation, the confirmed ORR was 44% (7 of 16)*
- *Preliminary Kaplan-Meier estimated median progression-free survival (mPFS) of 7.4 months, with a 6-month PFS rate of 62%*
- *The combination of PIKTOR with paclitaxel was generally well tolerated, with a treatment-related hyperglycemia rate of 12% (2% Gr. 3) and stomatitis rate of 21% (2% Gr. 3), and a discontinuation rate of 5% due to treatment-related adverse events*
- *Data support advancement of PIKTOR development into a Phase 3 registrational trial*
- *Webcast today at 8 a.m. ET*

AUSTIN, Texas--(BUSINESS WIRE)--Nov. 9, 2026-- Faeth Therapeutics (Nasdaq: FTH), a clinical-stage oncology company developing multi-node therapies for cancer patients, including its lead program PIKTOR, today announced topline clinical data from its Phase 2 trial (FTH-PIK-201; NCT06463028; GOG-3111) of PIKTOR, an investigational all-oral combination of serabelisib and sapanisertib, given with paclitaxel to patients with advanced endometrioid endometrial cancer and a PI3K/AKT/mTOR (PAM) pathway mutation who had received at least one prior line of therapy. The trial is being conducted in collaboration with The GOG Foundation, Inc. (GOG-F).

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The Phase 2 trial is ongoing, and the topline data include 42 patients with endometrioid endometrial cancer who had a median of 2 prior lines of therapy (range 1-4 lines). As of the October 30, 2026 efficacy data cut, confirmed objective responses were observed in 12 of the 36 efficacy-evaluable patients, for a confirmed objective response rate (ORR) of 33%. One additional patient had a partial response that could not be confirmed because the patient discontinued the study before a confirmatory scan, for an unconfirmed ORR of 36% (13 of 36). Among patients with a PIK3CA mutation, the confirmed ORR was 44% (7 of 16). In the 42 treated patients, the preliminary Kaplan-Meier estimated median progression-free survival (PFS) was 7.4 months (95% CI 5.3-NR), and the 6-month PFS rate was 62% (95% CI 43%-75%); 16 patients remained on treatment at the data cut.

“We believe these data support the multi-nodal PAM targeting hypothesis, whereby more complete inhibition of the pathway may drive durable responses and extend progression-free survival without the safety limitations of single-node inhibitors,” said Anand Parikh, Co-Founder and Chief Executive Officer of Faeth. “Endometrial cancer has among the highest rates of PI3K pathway alterations of any cancer, yet no drug that targets the pathway is approved to treat it.

“In PIK-201, PIKTOR delivered a preliminary estimated median PFS of 7.4 months, which we believe compares favorably to the 3-4 months typical for salvage chemotherapy alone, or the 6-7 months observed with newer treatments including TOPO1-based ADCs.” Mr. Parikh continued, “In our view, these preliminary data set PIKTOR apart. On the safety side, hyperglycemia and stomatitis were mostly low grade in a population in which nearly half of patients had diabetes or prediabetes and prophylactic steroid mouthwash was not required. We now plan to advance toward a Phase 3 trial, subject to regulatory alignment, with the goal of getting PIKTOR into the hands of patients as expeditiously as possible.”

“We need more treatment options for patients whose advanced endometrial cancer has progressed after platinum chemotherapy and immunotherapy,” said David Starks, MD, MPH, a PIK-201 and GOG Foundation principal investigator and Gynecologic Oncologist at Avera Cancer Institute, Sioux Falls, South Dakota. “I believe the response and progression-free survival data reported for PIKTOR with paclitaxel give physicians a reason to follow it closely. I am excited by the potential that this treatment could have for my patients.”

Phase 2 FTH-PIK-201 Topline Clinical Data Highlights

Baseline characteristics

- The open-label, single-arm Phase 2 trial (NCT06463028, GOG-3111) is evaluating patients with PIKTOR plus paclitaxel.
- 48% of patients had diabetes or pre-diabetes at baseline.
- 76% of patients had distant metastases, including liver and lung lesions.
- Patients had a median of 2 prior lines of therapy (range 1 to 4), with 3 or more prior lines in 15 patients (36%).
- All patients had been previously treated with taxane-based chemotherapy (100%), and prior immunotherapy was reported in 41 patients (98%).
- Of the 42 treated patients, 6 were not evaluable for efficacy, having discontinued prior to the first post-baseline scan due to

early disease progression (n=3) or non-treatment-related reasons (n=3).

Efficacy

As of the October 30, 2026 efficacy data cut:

- The confirmed ORR was 33% (12 of 36 efficacy-evaluable patients). One additional patient had a partial response that could not be confirmed because the patient discontinued the study before a confirmatory scan, for an unconfirmed ORR of 36% (13 of 36).
- Among patients with a PIK3CA mutation, the confirmed ORR was 44% (7 of 16).
- At the data cut, 9 of the 12 confirmed responders and 7 patients with a best response of stable disease remained on treatment. Several responses deepened over the course of therapy, including one patient who converted from stable disease to partial response after 20 months of treatment.
- The disease control rate (DCR) was 83% (30 of 36), defined as the percentage of patients with a best overall response of complete response, partial response or stable disease.
- In all 42 treated patients, the preliminary Kaplan-Meier estimated median PFS was 7.4 months (95% CI: 5.3 to NR), and the preliminary 6-month PFS rate was 62% (95% CI: 43% to 75%).

Safety

As of the October 23, 2026 safety data cut:

- Two patients (5%) discontinued treatment due to a treatment-related adverse event (TRAE; headache, dizziness). There were no treatment-related deaths.
- 64% of patients had a grade 3 or higher TRAE. Neutropenia, a grouped term including neutropenia and decreased neutrophil count, occurred in 36% of patients overall and was the most frequent grade 3 or higher TRAE (26%).
- Hyperglycemia TRAEs occurred in 5 of 42 patients (12%), and 1 patient (2%) had a grade 3 event. 48% of patients had diabetes or pre-diabetes at baseline.
- Stomatitis TRAEs occurred in 21% of patients, and 1 patient (2%) had a grade 3 event. Patients did not receive steroid mouthwash prophylaxis.

Webcast details

Faeth will host a webcast today, November 9, 2026, at 8:00 a.m. ET to discuss the data. David Starks, MD, MPH, Gynecologic Oncologist at Avera Cancer Institute, Sioux Falls, South Dakota, will join management. To access the live webcast, click here. A replay will be available in the Events and Presentations (Events and Presentations —Faeth Therapeutics, Inc) section of Faeth's corporate website.

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.

About The GOG Foundation, Inc. (www.gog.org)

The GOG Foundation, Inc. is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of gynecologic oncology. The GOG Foundation is committed to maintaining the highest standards in clinical trial development, execution, analysis, and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancer of the ovary (including surface peritoneal malignancies), uterus (including endometrium, soft tissue sarcoma, and gestational trophoblastic neoplasia), cervix, and vulva. The GOG Foundation is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, oncology nurses, biostatisticians (including those with expertise in bioinformatics), basic scientists, quality of life experts, data managers, and administrative personnel.

About the GOG Partners Program

Supported by industry, the GOG Partners program is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners program promotes the mission of the GOG Foundation dedicated to transforming the care in gynecologic oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network, and has led to several FDA approvals.

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 Company’s expectations regarding its pipeline and development plans, including the Phase 2 trial of PIKTOR in combination with paclitaxel (PIK-201) in advanced endometrial cancer and the Phase 1b/2 trial of PIKTOR in HR+/HER2- advanced breast cancer; the data from the Phase 2 trial of PIKTOR in advanced endometrial cancer, which may change as scans are confirmed and patients remain on study; the potential design and timing of a Phase 3 trial; and the potential therapeutic benefits, tolerability profile and differentiation of PIKTOR.

PIKTOR is investigational; its safety and efficacy have not been established, and it has not been approved by any regulatory authority. The PIK-201 results are preliminary and reflect the specified data cutoffs and analysis populations. Results may change with additional follow-up, data verification and analysis. PIK-201 is a single-arm combination study and does not establish the contribution of individual components or comparative safety or efficacy.

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 outcome of interactions with regulatory authorities; 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, as amended, its Quarterly Reports on Form 10-Q filed with the SEC on May 15, 2026, August 4, 2026 and 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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