



Faeth Presents Updated Preclinical Data at ESMO, including First-Ever Head-to-Head Characterization of PIKTOR against Gedatolisib

October 23, 2026

In two preclinical breast cancer xenograft models (abstract #431P), PIKTOR inhibited tumor growth to a comparable or greater extent than intravenous gedatolisib

PIKTOR inhibited HR+/HER2- breast cancer xenograft tumor growth in models with and without a PIK3CA mutation, the same population FTH-PIK-101 enrolls

In mouse xenograft models, PIKTOR in combination with fulvestrant and palbociclib achieved complete tumor growth inhibition or tumor regression. This combination is being tested in FTH-PIK-101

In a kinase assay, PIKTOR inhibited AKT more deeply than single-node PAM inhibitors at clinically relevant concentrations

These data lend support for Faeth's multi-node strategy, with two upcoming readouts: FTH-PIK-201 topline data in second-line advanced endometrial cancer by year-end 2026 and FTH-PIK-101 interim data in HR+/HER2- advanced breast cancer in 2027

AUSTIN, Texas--(BUSINESS WIRE)--Oct. 23, 2026-- Faeth Therapeutics (Nasdaq: FTH), a clinical-stage oncology company developing multi-node therapies for cancer patients, including its lead program PIKTOR, today announced presentation of preclinical data at the European Society for Medical Oncology (ESMO) Congress 2026 in Madrid, Spain, in a poster entitled "Characterising the efficacy of multi-node PI3K/AKT/mTOR pathway inhibition with serabelisib and sapanisertib (PIKTOR) in combination with SERDs and a CDK4/6 inhibitor in models of HR+/HER2- breast cancer."

These data support the design of FTH-PIK-101, the ongoing Phase 1b/2 clinical trial of PIKTOR with fulvestrant and/or other anticancer therapies in HR+/HER2- advanced breast cancer. In xenograft models with and without a PIK3CA mutation, oral PIKTOR inhibited tumor growth to a comparable or greater extent than intravenous gedatolisib. In combination with fulvestrant and palbociclib, standard-of-care treatments for HR+/HER2- breast cancer, PIKTOR completely inhibited tumor growth. In a cell-derived assay, PIKTOR achieved a greater degree of AKT kinase inhibition compared to single-node inhibitors, including other alpha-selective PI3K and/or mTOR inhibitors. Faeth believes these findings support the potential for an all-oral, multi-node option to improve on the standard of care in breast cancer, and expects FTH-PIK-201 topline data in second-line advanced endometrial cancer by year-end 2026 and FTH-PIK-101 interim data in 2027.

"These data strengthen our conviction that oral multi-node inhibition of the PI3K/AKT/mTOR pathway is achievable and that PIKTOR can work alongside standard of care," said Anand Parikh, Chief Executive Officer of Faeth Therapeutics. "In HR+/HER2- advanced breast cancer, we believe PIKTOR may offer patients an all-oral option designed to address the limits of single-node inhibitors, and it could give Faeth a differentiated position relative to gedatolisib, another multi-node inhibitor which is intravenous by design. We believe we can translate this science into clinical evidence, with topline data from our Phase 2 FTH-PIK-201 trial in second-line advanced endometrial cancer by year-end 2026 and interim data from our Phase 1b/2 FTH-PIK-101 trial in breast cancer in 2027."

Data summary

Xenograft studies in mice with human breast cancer tumors

- **Design:** Faeth ran four studies in mice implanted with human HR+/HER2- breast cancer cells: two with MCF7 cells, which carry a PIK3CA mutation, and two with HCC1428 cells, which do not. After tumors formed, mice received PIKTOR, gedatolisib, palbociclib, fulvestrant, or combinations of these.
- **PIKTOR alone:** PIKTOR slowed tumor growth compared with no treatment in both tumor types.
- **PIKTOR versus gedatolisib:** In the MCF7 model, tumor growth inhibition was comparable. In the HCC1428 model, PIKTOR achieved greater tumor growth inhibition than gedatolisib with or without the combination of fulvestrant and palbociclib.
- **Combinations:** PIKTOR enhanced the activity of fulvestrant and palbociclib. The triple combination halted tumor growth in the HCC1428 model and shrank tumors in the MCF7 model.

Pathway assays

- **AKT activity:** In cell lysates, PIKTOR reduced AKT activity to ~10% of uninhibited levels, a deeper reduction than any of the other PI3K and/or mTOR inhibitors tested. AKT is a central signaling node downstream of PI3K along the PAM axis that tumors rely on for growth and survival.
- **Phosphorylation assay:** In both breast cancer cell lines, Faeth measured PIKTOR's ability to alter phosphorylation levels of key PAM nodes (PI3K, AKT, and mTOR). Phosphorylation status is another measure of pathway activity. PIKTOR suppressed phospho-AKT, phospho-S6, and phospho-4E-BP1, consistent with its design to block the PI3K/AKT/mTOR

pathway at more than one point.

The poster is available on the Publications tab of the Faeth website at <https://www.faeththerapeutics.com/science#publications>.

Presentation Details:

Title: Characterising the efficacy of multi-node PI3K/AKT/mTOR pathway inhibition with serabelisib and sapanisertib (PIKTOR) in combination with SERDs and CDK inhibitors in models of HR+/HER2- breast cancer

Abstract Number: 431P

Session: Basic Science Poster Session

Date: Friday, October 23, 2026

Location: Poster Area - Hall 5

Time: 15:15 - 16:00 CEST

Presenter: Oliver D. K. Maddocks, PhD, Co-Founder & Chief Scientific Officer of Faeth Therapeutics

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. This multi-node approach is designed to address the signaling feedback reactivation and treatment-emergent resistance mutations that may limit the efficacy of single-node PI3K/AKT/mTOR pathway inhibitors. According to published literature, the PAM 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 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 significance and interpretation of the preclinical data presented at the ESMO Congress 2026, including comparisons of PIKTOR to gedatolisib and to other single-node PI3K/AKT/mTOR pathway inhibitors; 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 by year-end 2026, and the Phase 1b/2 trial of PIKTOR in HR+/HER2- advanced breast cancer and the anticipated timing of interim data in 2027; the potential therapeutic benefits, tolerability profile and differentiation of PIKTOR, including relative to gedatolisib and single-node inhibitors; and the Company's expectations regarding its multi-node strategy and its potential to improve on the standard of care in breast and endometrial cancer.

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 risk that results from preclinical studies, including comparisons with other product candidates or approved products, may not be predictive of results in ongoing or future 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 August 4, 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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