Sensei Biotherapeutics Doses First Patient in Phase 1b/2 Trial of PIKTOR in HR+/HER2- Advanced Breast Cancer

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PIKTOR is an investigational all-oral, multi-node inhibitor targeting escape routes in the PI3K/AKT/mTOR pathway that single-node inhibitors leave open

BOSTON--(BUSINESS WIRE)--May 5, 2026-- Sensei Biotherapeutics, Inc. (Nasdaq: SNSE), a clinical-stage biotechnology company, announced today that the first patient was dosed in Study FTH-PIK-101 (NCT07558733), a Phase 1b/2 trial of PIKTOR in patients with HR+/HER2- advanced breast cancer. PIKTOR, an investigational, all-oral combination of serabelisib and sapanisertib, is designed to inhibit multiple nodes of the PI3K/AKT/mTOR pathway through PI3K-alpha and dual mTORC1/2 targeting, and became Sensei's lead program after the company acquired Faeth Therapeutics in February 2026.

Patients with HR+/HER2- advanced breast cancer whose tumors stop responding to current therapies have few effective options, particularly when their cancer is driven by the PI3K/AKT/mTOR signaling pathway, a network of growth and survival signals that is altered in approximately half of HR+/HER2- cases.[1] Study FTH-PIK-101, titled "Open-Label Umbrella Study to Evaluate Safety and Efficacy of Sapanisertib and Serabelisib (PIKTOR) in Various Combinations in Patients with HR+/HER2- Advanced or Metastatic Breast Cancer," is evaluating PIKTOR across HR+/HER2-advanced breast cancer patients, regardless of mutational status.

The study is a multi-center, dose-escalation Phase 1b/2 trial evaluating sapanisertib and serabelisib (PIKTOR) in combination with fulvestrant and/or other anticancer therapies in patients with HR+/HER2- advanced or metastatic breast cancer.

Approved drugs that target this pathway each block only one component, which often allows the cancer to reroute its growth signals through the parts that remain active. PIKTOR takes a different approach, combining two oral drugs, serabelisib (which blocks PI3K-alpha) and sapanisertib (which blocks mTORC1 and mTORC2), to target multiple nodes of the pathway simultaneously.

PIKTOR has already been tested in cancer patients. In a completed investigator-initiated Phase 1b study (NCT03154294), patients with advanced breast, endometrial and ovarian tumors who had failed an average of four prior treatments and were largely out of standard options received PIKTOR plus paclitaxel. Nearly half responded (47% overall response rate, n=15). Among patients whose tumors carried PI3K pathway mutations, 71% responded. Three patients had complete responses, all in endometrial cancer.[2] Sapanisertib in combination with fulvestrant has also shown activity in HR+/HER2- advanced breast cancer in an earlier Phase 2 study.[3]

"In our earlier trial, patients who had exhausted multiple lines of therapy, including chemotherapy, responded to the PIKTOR plus paclitaxel combination, and several had complete responses," said Anand Parikh, Chief Operating Officer of Sensei Biotherapeutics. "PIK-101 now takes that same oral combination into breast cancer, where a large share of tumors carry the pathway alterations that PIKTOR is designed to target."

As part of its broader clinical development program for PIKTOR, Sensei is also conducting Study FTH-PIK-201, an ongoing multicenter, open-label, single-arm Phase 2 study (n≈40) in patients with advanced endometrial cancer.

About Sensei Biotherapeutics

Sensei Biotherapeutics, Inc. (Nasdaq: SNSE) is a clinical-stage biotechnology company focused on improving outcomes for cancer patients through multi-node inhibition of critical oncogenic pathways. Following the acquisition of Faeth Therapeutics, Sensei's lead program is PIKTOR, an investigational multi-node inhibitor of the PI3K/AKT/mTOR pathway in development for endometrial and breast cancer. Sensei is also completing a Phase 1/2 trial of solnerstotug, its V-domain Ig suppressor of T cell activation (VISTA) inhibitor, in patients with advanced solid tumors. Sensei intends to use its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. For more information, please visit www.senseibio.com and follow the company on X @SenseiBio and LinkedIn.

About PIKTOR

PIKTOR is an investigational all-oral combination of serabelisib and sapanisertib that inhibits multiple nodes of the PI3K/AKT/mTOR pathway, including PI3K-alpha and dual mTORC1/2. In a completed Phase 1b trial, PIKTOR plus paclitaxel demonstrated an overall response rate of 47% in response-evaluable patients (n=15), averaging four prior lines of therapy (range 1–12), with a 71% response rate in patients with PI3K pathway mutations, including three complete responses, all in endometrial cancer. PIKTOR is currently in clinical development for endometrial and breast cancer.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this press release, other than purely historical information, may constitute "forward-looking statements"

within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, concerning Sensei. These forward-looking statements include, but are not limited to, express or implied statements relating to the company's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: expectations regarding or plans for the company's pipeline, including its ongoing clinical trials, research and development programs and the expected timing for key milestones; and the potential benefits of PIKTOR. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "opportunity," "potential," "milestones," "pipeline," "can," "goal," "aim," "strategy," "target," "seek," "anticipate," "achieve," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "predict," "project," "should," "will," "would" and similar expressions (including the negatives of these terms or variations of them) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting the company will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond the company's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to those uncertainties and factors described under the heading "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 well as discussions of potential risks, uncertainties, and other important factors included in other filings by the company from time to time, as well as risk factors associated with companies that operate in the biotechnology industry. Should one or more of these risks or uncertainties materialize, or should any of the company's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. The company does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in the company.

[1] Bhave, Manali A., et al. *Comprehensive genomic profiling of ESR1, PIK3CA, AKT1, and PTEN in HR(+)HER2(−) metastatic breast cancer: Prevalence along treatment course and predictive value for endocrine therapy resistance in real-world practice*. Breast Cancer Research and Treatment. 2024;207(3):599–609.

[2] Sensei Biotherapeutics, "Sensei Biotherapeutics Announces Acquisition of Faeth Therapeutics and $200 Million Concurrent Private Placement," February 18, 2026; and Starks DC, Rojas-Espaillat L, Meissner T, Williams CB. *Phase I dose escalation study of dual PI3K/mTOR inhibition by sapanisertib and serabelisib in combination with paclitaxel in patients with advanced solid tumors. Gynecologic Oncology.* 2022;166(3):403-409.

[3] García-Sáenz JA, et al. *Sapanisertib plus fulvestrant in postmenopausal women with estrogen receptor-positive/HER2-negative advanced breast cancer after progression on aromatase inhibitor. Clinical Cancer Research.* 2022;28(6):1107-1116; and Juric D, et al. *A first-in-human, phase I, dose-escalation study of TAK-117, a selective PI3Kα isoform inhibitor, in patients with advanced solid malignancies. Clinical Cancer Research.* 2017;23(17):5015-5023.

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