



Verastem Oncology Announces Positive Updated Results from RAMP 205 Evaluating Avutometinib Plus Defactinib in Combination with Standard-of-Care Chemotherapy in First-Line Metastatic Pancreatic Cancer

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90% of patients in the study presented with metastatic (Stage IV) disease at diagnosis

6-month overall survival rate was 86%; follow-up continues and survival data continue to mature

BOSTON--(BUSINESS WIRE)--Jun. 17, 2026-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with RAS/MAPK pathway-driven cancers, today announced positive updated safety and efficacy results from the RAMP 205 Phase 1b/2a Recommended Phase 2 Dose (RP2D) cohort of 29 patients evaluating avutometinib plus defactinib in combination with gemcitabine and nab-paclitaxel in first-line metastatic pancreatic ductal adenocarcinoma (PDAC).

KRAS is mutated in more than 90% of pancreatic cancers, making it a key driver of tumor growth. The RAMP 205 trial was designed to evaluate whether simultaneous inhibition of KRAS-driven signaling and FAK-mediated resistance pathways, in combination with standard-of-care chemotherapy, could improve outcomes for patients living with metastatic pancreatic cancer.

"The updated data from the RAMP 205 trial provide important clinical insights into the potential impact of combined RAF/MEK and FAK inhibition as a therapeutic option for pancreatic cancer. While pancreatic cancer remains one of the most challenging cancers to treat, the early survival trends and deep responses observed in this study indicate that avutometinib and defactinib are combinable with standard-of-care chemotherapy and may help overcome resistance mechanisms inherent in pancreatic cancer and support further exploration of strategies designed to address oncogenic signaling and mechanisms of treatment resistance," said John Hayslip, M.D., chief medical officer at Verastem Oncology. "We are grateful to PanCAN, the RAMP 205 investigators, and especially the patients and families who participated in the trial."

In the Phase 1b/2a study, 29 patients were enrolled and treated at the RP2D with avutometinib 2.4 mg twice weekly (BIW), defactinib 200 mg twice daily (BID) for 3 weeks on and one week off, and gemcitabine (800 mg/m²) plus nab-paclitaxel (125 mg/m²) administered on Days 1, 8, and 15 of each 28-day cycle. At diagnosis, 90% of patients presented with metastatic disease. As of the June 5, 2026 data cutoff, with a median follow up of 9.8 months, the combination demonstrated encouraging clinical activity, including an 86% overall survival (OS) rate at 6 months, with the OS data continuing to mature. The progression-free survival (PFS) rate at 6 months was 68%, and the confirmed objective response rate (ORR) was 52% (15/29). At the RP2D dose, the majority (83%) of patients experienced tumor shrinkage. Nine patients remain on treatment at this dose level. Adverse events remained generally consistent with the previously reported safety and tolerability profile, with no new safety signals observed.

"For patients and their families facing a pancreatic cancer diagnosis, every advance in research and understanding of the underlying biology driving this cancer matters," said Anna Berkenblit, M.D., chief scientific and medical officer of the Pancreatic Cancer Action Network (PanCAN). "We awarded Verastem the PanCAN Therapeutic Accelerator Award in 2022 to invest in research and development of novel treatment approaches. The results of the RAMP 205 trial underscore the importance of continued research in the RAS/MAPK-pathway to help improve outcomes for patients living with pancreatic cancer."

"We will continue to evaluate the potential role of avutometinib plus defactinib in metastatic pancreatic cancer, including future development opportunities and potential strategic collaborations, informed by the final overall survival results from the study as well as emerging data from VS-7375, our investigational potential best-in-class oral KRAS G12D (ON/OFF) inhibitor, currently being evaluated in metastatic pancreatic cancer as both a monotherapy and in combination regimens," said Dan Paterson, president and chief executive officer of Verastem Oncology. "We will also assess opportunities to share these data in the future, including at a medical meeting."

[In May 2022](#), Verastem Oncology was selected by PanCAN to receive the inaugural PanCAN Therapeutic Accelerator Award, supporting evaluation of avutometinib in combination with defactinib in front-line metastatic pancreatic cancer. Designed to accelerate the development of new pancreatic cancer treatments, the award provided Verastem with \$3.8M following a rigorous, competitive process involving scientific, business, and programmatic review from leading experts in the field. In parallel, a working group led by PanCAN was formed as a partnership between Verastem and the academic community to further understand the science behind and the potential of this investigational treatment combination to improve outcomes for patients.

About Metastatic Pancreatic Cancer

Pancreatic cancer is the third leading cause of cancer-related death in the U.S. and seventh leading cause of cancer-associated mortality worldwide. Metastatic pancreatic cancer, or stage IV disease, occurs when the cancer spreads beyond the pancreas to distant organs. More than 90% of pancreatic cancers harbor KRAS mutations, underscoring the central role of KRAS in the development and the progression of the disease. Approximately 40% of pancreatic tumors harbor a KRAS G12D mutation, the most prevalent subtype in pancreatic cancer. Patients with KRAS G12D-mutant tumors often have poorer outcomes, underscoring the need for therapies designed specifically to inhibit this mutation potently and for a long duration. Each year, more than 30,000 people in the U.S. and over 240,000 people globally are diagnosed with metastatic pancreatic cancer. There has been minimal progress with treatment, and the five-year survival rate remains approximately 3%. Current treatment approaches may include surgery, chemotherapy, radiation therapy, targeted therapies, or a combination of these modalities.

About RAMP 205 Phase 1b/2a Study

RAMP 205 is a multicenter, open-label, single arm Phase 1b/2a study to evaluate the safety, tolerability, and efficacy of avutometinib and defactinib in combination with standard of care chemotherapy (gemcitabine and nab-paclitaxel) in patients with previously untreated metastatic pancreatic ductal adenocarcinoma. Part A of the study evaluated varied dose and schedule combinations to determine the recommended Phase 2 dose for expansion into Part B. RAMP 205 is supported by a PanCAN Therapeutic Accelerator Award.

About AVMAPKI and FAKZYNJA Combination Therapy

AVMAPKI (avutometinib) inhibits MEK kinase activity while also blocking the compensatory reactivation of MEK by upstream RAF. RAF and MEK proteins are regulators of the RAS/RAF/MEK/ERK (MAPK) pathway. Blocking RAF and/or MEK activates FAK, a key mediator of drug resistance. FAKZYNJA (defactinib) is a FAK inhibitor and together, the avutometinib and defactinib combination was designed to provide a more complete blockade of the signaling that drives the growth and drug resistance of RAS/MAPK pathway-dependent tumors.

The U.S. Food and Drug Administration (FDA) approved AVMAPKI® FAKZYNJA® CO-PACK (avutometinib capsules; defactinib tablets) for the treatment of adult patients with KRAS-mutated recurrent LGSOC who have received prior systemic therapy on May 8, 2025. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Verastem is conducting RAMP 301 (GOG-3097/ENGOT-ov81/GTG-UK) (NCT06072781), an international Phase 3 confirmatory trial evaluating the combination of avutometinib and defactinib versus standard chemotherapy or hormonal therapy for the treatment of recurrent low-grade serous ovarian cancer (LGSOC) with and without a KRAS mutation. Verastem is also evaluating avutometinib plus defactinib with standard-of-care chemotherapy as a potential treatment in the first-line for patients with advanced pancreatic cancer (RAMP 205; NCT05669482). Avutometinib and defactinib are not approved by the FDA or any other regulatory authority, either in combination or with other therapies, for any of these investigative uses. Neither avutometinib nor defactinib are approved by the FDA or any other regulatory authority on a stand-alone basis for any use.

AVMAPKI FAKZYNJA CO-PACK U.S. Indication

Indication

AVMAPKI FAKZYNJA CO-PACK is indicated for the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information

Warnings and Precautions

- **Ocular Toxicities:** Ocular toxicities, including visual impairment and vitreoretinal disorders, occurred. Perform comprehensive ophthalmic evaluation at baseline, prior to cycle 2, every three cycles thereafter, and as clinically indicated. Withhold AVMAPKI FAKZYNJA CO-PACK for ocular toxicities until improvement at the same or reduced dose. Permanently discontinue AVMAPKI FAKZYNJA CO-PACK for any grade 4 toxicity.
- **Serious Skin Toxicities:** Skin toxicities, including photosensitivity and severe cutaneous adverse reactions (SCARs) occurred. Adhere to concomitant medications. Monitor for skin toxicities and interrupt, reduce or permanently discontinue AVMAPKI FAKZYNJA CO-PACK based on severity, tolerability and duration.
- **Hepatotoxicity:** Monitor liver function tests prior to each cycle, on day 15 of the first 4 cycles, and as clinically indicated. Withhold, reduce or discontinue AVMAPKI FAKZYNJA CO-PACK based on severity and persistence of abnormality.
- **Rhabdomyolysis:** Monitor creatine phosphokinase prior to the start of each cycle, on day 15 of the first four cycles, and as clinically indicated. If increased CPK occurs, evaluate patients for rhabdomyolysis or other causes. Withhold, reduce or permanently discontinue AVMAPKI FAKZYNJA CO-PACK based on severity and duration of the adverse reaction.
- **Embryo-Fetal Toxicity:** AVMAPKI FAKZYNJA CO-PACK can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Adverse Reactions

The most common ($\geq 25\%$) adverse reactions, including laboratory abnormalities, were increased creatine phosphokinase, nausea, fatigue, increased aspartate aminotransferase, rash, diarrhea, musculoskeletal pain, edema, decreased hemoglobin, increased alanine aminotransferase, vomiting, increased blood bilirubin, increased triglycerides, decreased lymphocyte count, abdominal pain, dyspepsia, dermatitis acneiform, vitreoretinal disorders, increased alkaline phosphatase, stomatitis, pruritus, visual impairment, decreased platelet count, constipation, dry skin, dyspnea, cough, urinary tract infection, and decreased neutrophil count.

Drug Interactions

- **Strong and moderate CYP3A4 inhibitors:** Avoid concomitant use with AVMAPKI FAKZYNJA CO-PACK.
- **Strong and moderate CYP3A4 inducers:** Avoid concomitant use with AVMAPKI FAKZYNJA CO-PACK.
- **Warfarin:** Avoid concomitant use of AVMAPKI FAKZYNJA CO-PACK with warfarin and use an alternative to warfarin.
- **Gastric acid reducing agents:** Avoid concomitant use of AVMAPKI FAKZYNJA CO-PACK with proton pump inhibitors (PPIs) or H2 receptor antagonists. If use of an acid-reducing agent cannot be avoided, administer FAKZYNJA 2 hours before or 2 hours after the administration of a locally acting antacid.

Use in Specific Populations

- **Lactation:** Advise not to breastfeed.
- **Fertility:** May impair fertility in males and females.

Click here for full [Prescribing Information](#).

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a biopharmaceutical company committed to developing and commercializing new medicines to improve the lives of patients diagnosed with RAS/MAPK pathway-driven cancers. Verastem markets AVMAPKI® FAKZYNJA® CO-PACK in the U.S. Our pipeline is focused on novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition, FAK inhibition, and KRAS G12D inhibition. For more information, please visit www.verastem.com and follow us on [LinkedIn](#).

Forward-Looking Statements

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "may," "believe," "estimate," "forecast," "goal," "project," and other words of similar meaning. Such forward-looking statements address various matters about, among other things, Verastem Oncology's programs and product candidates, strategy, future plans and prospects, including statements related to the potential for and timing of commercialization of product candidates, the expected outcome and benefits of the Company's collaboration with GenFleet Therapeutics (Shanghai), Inc., the timing of commencing and completing trials and compiling data, the expected timing of the presentation of data by the Company and the potential clinical value of various of the Company's clinical trials. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: the uncertainties inherent in research and development, such as the possibility of negative or unexpected results of clinical trials; that we may not see a return on investment on the payments we have and may continue to make pursuant to the collaboration and option agreement with GenFleet, or that GenFleet may fail to fully perform under the agreement; that we may not be successful in our continued commercialization of AVMAPKI FAKZYNJA CO-PACK; that the development and commercialization of our product candidates may take longer or cost more than planned, including as a result of conducting additional studies or our decisions regarding execution of such commercialization; that data may not be available when expected; risks associated with preliminary and interim data, which may not be representative of more mature data; risks associated with the recent changes in administration policy or actions that may create regulatory uncertainty that may adversely affect our business; risks associated with the current administration's reductions to the FDA's workforce and any subsequent reductions that may lead to disruptions and delays in the FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development programs; that our product candidates may not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients; and the risks identified under the heading "Risk Factors" as detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission (SEC) on March 4, 2026, as well as the other information we file with the SEC, are possibly realized. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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