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Sumitomo Pharma America Presents First Clinical Data for SMP-3124LP, an Investigational PEGylated Liposome CHK1 Inhibitor, at ASCO 2026

First-in-human preliminary results showed SMP-3124LP was generally well-tolerated with manageable safety profile in patients with heavily pretreated advanced solid tumors

Early signals of clinical activity observed with a 48.2% disease control rate (DCR) and five partial responses (PR)

MARLBOROUGH, Mass., June 1, 2026– Sumitomo Pharma America, Inc. (SMPA) today announced clinical data from its ongoing first-in-human Phase 1/2 trial of SMP-3124LP (NCT06526819). SMP-3124LP is a structurally distinct, investigational, selective checkpoint kinase 1 (CHK1) inhibitor delivered via a PEGylated liposome formulation. Designed with the specific goal of treating malignancies characterized by high replication stress, these findings were presented as a poster at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.

“Historically, the development of CHK1 inhibitors has been hampered by significant low blood counts and a narrow therapeutic window, which has limited their clinical utility for patients,” said Timothy A. Yap, MBBS, PhD, Professor of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center and lead investigator of the study. “By using this liposomal delivery method, we are attempting to address the primary obstacles that have previously stalled the CHK1 inhibitor mechanism of action. For patients who have already navigated multiple lines of therapy, this approach may offer the potential for meaningful clinical benefit and disease control without the overwhelming burden of side effects common to older therapies.”

Encouraging antitumor activity in heavily pretreated malignancies
The phase 1 part of the study enrolled 61 patients with selected advanced solid tumors across four intravenous (IV) doses: 20, 40, 60, and 90 mg/m^2 given every two weeks. The study population was heavily pretreated, with 37.7% of participants treated with more than four prior lines of therapy. SMP-3124LP demonstrated promising signals of antitumor activity (as of April 03, 2026.)

Among the 56 efficacy-evaluable patients, the study reported a 48.2% disease control rate (DCR). This included five RECIST v1.1 partial responses (PR) and 22 patients with stable disease (SD). The clinical significance of these results is underscored by responses in difficult-to-treat cancers. Partial responses were observed in 2 patients with platinum-resistant ovarian cancer (PROC), 2 with squamous cell carcinoma of the anus (SCCA), and 1 with colorectal cancer harboring an *FBXW7* mutation (this mutation is linked to poorer outcomes). Furthermore, 2 additional PROC patients achieved stable disease with tumor shrinkage of 20% or more, including one patient who experienced a -88% cancer antigen-125 (CA-125) response.

Preliminary results show liposomal delivery widened the therapeutic window with a manageable safety profile
The Phase 1/2 results show that SMP-3124LP was generally well tolerated with a manageable safety profile. No dose-limiting toxicities (DLTs) were observed at the lower dose levels of 20 or 40 mg/m^2. While DLTs including Grade 4 thrombocytopenia and Grade 3 febrile neutropenia were noted at higher doses (60 and 90 mg/m^2), the blood-related side effects (low blood counts) were generally transient and did not lead to any treatment discontinuations.

These findings suggest the liposomal delivery system may minimize drug exposure to healthy tissues while optimizing delivery to tumors. Infusion-related reactions (IRR), reported in 41% of patients, were all Grade 1/2 and manageable through standard supportive care or adjusted infusion rates. Additionally, pharmacokinetic data validated the therapeutic approach, long half-life (24-28 hr), and low volume of distribution (2.00-2.67 L) are consistent with liposomal formulation. Dose-proportional increases in exposure were observed across all levels tested.

“We are proud to present our first-in-human data for SMP-3124LP at ASCO—where the most rigorous advancements in oncology are shared—as it reinforces our focus on addressing some of the most persistent challenges in cancer treatment,” said Tsutomu Nakagawa, Ph.D., President and Chief Executive Officer of SMPA.

“With SMP-3124LP, we are developing a technology platform at SMPA based on liposomal delivery of targeted therapies in an effort to maximize the therapeutic window and minimize toxicities,” said Jatin Shah, M.D., Chief Medical Officer, Oncology, SMPA. “These are the first data in this first-in-human study of SMP-3124 where we have demonstrated the potential ability to deliver selective CHK1 inhibition with less myelosuppression, which has been the major AE limiting the ability to target CHK1 directly to the tumor while sparing the patient’s healthy cells. These data are a reflection of our efforts toward realizing sustainable and effective therapeutic options for those facing the complexities of difficult-to-treat cancers, including advanced solid tumors.”

CHK1 is an essential enzyme in the DNA damage response pathway that helps cancer cells repair their DNA to survive under high replication stress. While blocking CHK1 has long been a goal for oncologists, prior inhibitors were often toxic to healthy bone marrow, limiting their clinical utility. SMP-3124LP seeks to overcome this hurdle by using liposomal technology to widen the therapeutic window (the gap between an effective dose and a toxic one). This advancement may potentially unlock CHK1 inhibition for patients with few remaining treatment options.

Presentation Details

- **Abstract Number:** 3081
- **Abstract title:** First data disclosure from the first-in-human phase 1/2 trial of SMP-3124LP, the first investigational pegylated liposome CHK1 inhibitor, in patients with selected advanced solid tumors
- **Session title:** Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology

About SMP-3124LP

SMP-3124LP is a structurally distinct, investigational, selective checkpoint kinase 1 (CHK1) inhibitor delivered via a PEGylated liposome formulation. CHK1 is a key regulator of the DNA damage response; SMP-3124LP is designed with the goal of inhibiting this protein to induce DNA damage and promote apoptosis (cell death) in cancer cells with high replication stress. The use of liposomal technology may potentially widen the therapeutic window by maximizing drug delivery to tumors while minimizing exposure to healthy tissues, potentially reducing treatment emergent adverse events (TEAEs).

About Sumitomo Pharma

Sumitomo Pharma Co., Ltd. is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.) focused on addressing patient

needs in oncology, urology, women's health, rare diseases, cell & gene therapies and CNS. With products in the U.S., Canada, and Europe, and a diverse pipeline of early- to late-stage assets, we aim to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information on SMPA, visit our website https://www.us.sumitomo-pharma.com or follow us on LinkedIn.

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