SDK Therapeutics Announces Completion of Enrollment in the Pharmacokinetic Trial of SDK001 (Oral Solution of Arsenic Trioxide) in Patients with Acute Promyelocytic Leukemia

Mount Freedom, NJ – May 28, 2025 – SDK Therapeutics, Inc. ("SDK Therapeutics"), a clinical-stage biopharmaceutical company, today announced the completion of patient enrollment in its Pharmacokinetic (PK) Trial (SDKARS-101) of SDK001, an oral solution of arsenic trioxide (ATO), in patients with Acute Promyelocytic Leukemia (APL).

"*We are proud to announce the completion of patient recruitment in SDKARS-101, our first company-sponsored clinical trial, less than three months after enrolling the first patient*," said Stéphane Berthier, PharmD, Chief Executive Officer of SDK Therapeutics. "*I would like to extend my sincere thanks to Dr. Harry Gill, his clinical team at The University of Hong Kong, and the patients and families who made this rapid enrollment possible. We remain on schedule to analyze the trial results this summer and are preparing to launch our global Phase 3 registrational trial by the end of 2025*."

SDKARS-101 is a randomized, open-label, single-dose, 4-period cross-over trial designed to evaluate the PK of SDK001 compared to intravenous (IV) ATO, currently the standard of care for APL. The trial also assesses SDK001 under fasting and fed conditions, as well as its interaction with calcium carbonate. SDK001 as an oral solution of ATO, is intended to provide a more convenient and patient-centered alternative to IV ATO, which typically involves up to 140 infusions over a 10-month treatment period. By enabling at-home oral administration, SDK001 has the potential to reduce the treatment burden on patients, lower healthcare system demands, and minimize risks associated with repeated IV access. Data from this PK trial will inform the sample size of the upcoming Phase 3 registrational trial, in newly diagnosed APL patients to be initiated in Q4 2025.

"It is exciting to prepare to analyze the final data from this important bridging study to our phase 3 trial, in our effort to bring forward SDK001 to patients in the United States and Europe" said Danelle James, M.D., Chief Medical Officer at SDK Therapeutics. "*We are grateful to the University of Hong for the formative work on SDK001 and the large body of clinical data that has facilitated our rapid movement*."

About Acute Promyelocytic Leukemia

Acute promyelocytic leukemia (APL) accounts for approximately 5–10% of patients with acute myeloid leukemia (AML) and is characterized by the balanced translocation t(15;17)(q24;q21), resulting in the formation of PML-RARA fusion gene. The combination therapy of all-trans retinoic acid (ATRA) and ATO has shown to be highly effective, achieving durable remission rates in more than 80% in patients with APL[1]. This combination therapy is the standard treatment for adult patients with de novo, non-high-risk APL.

A Potential New Standard-of-Care Therapy with the Product

Currently, Arsenic Trioxide is approved in North America and Europe exclusively as an IV formulation, which places a considerable treatment burden on patients. The standard IV regimen requires up to 140 infusions, each lasting two to four hours, over the course of induction and consolidation therapy posing significant logistical, emotional, and financial challenges for patients and caregivers.

SDK001 is a novel oral liquid formulation of ATO, developed as a more patient-centered alternative. It has already received regulatory approval in Hong Kong for the treatment of APL and has been administered to more than 400 patients across both newly diagnosed and relapsed settings. Clinical data from these trials have demonstrated a favorable long-term safety and efficacy profile. Administered once daily, SDK001 offers a simplified treatment experience and has the potential to replace IV ATO as the new standard of care for patients with APL.

By eliminating the need for frequent hospital visits, SDK001 provides a more convenient route of administration, significantly reduces the treatment burden, and enhances quality of life for patients. Furthermore, its oral delivery format can improve treatment accessibility particularly in geographically underserved areas and has the potential to lower overall healthcare system burden.

In recognition of its potential to address a critical unmet need in a rare disease, SDK001 was granted Orphan Drug Designation (ODD) by both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in 2024.

In January 2025, the FDA cleared the Investigational New Drug (IND) application for SDK001 Oral Solution for the treatment of APL. The clearance allowed SDK Therapeutics to proceed with its proposed clinical development program, marking a key regulatory milestone on the path toward global registration.

About SDK Therapeutics, Inc.

SDK Therapeutics, Inc. is a New Jersey based biotechnology company founded in 2024 with a mission to develop and commercialize medicines in hematology, oncology, and rare diseases to improve the life of patients.

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1 Gill, H. *et al.* Oral arsenic trioxide incorporation into frontline treatment with all-trans retinoic acid and chemotherapy in newly diagnosed acute promyelocytic leukemia: A 5-year prospective study. *Cancer* 125, 3001-3012, doi:10.1002/cncr.32180 (2019).