SDK Therapeutics Announces Poster Presentation of Oral Arsenic Trioxide at the 67th American Society of Hematology (ASH) Annual Meeting

Parsippany, NJ – November 3rd, 2025 – SDK Therapeutics, Inc. ("SDK Therapeutics"), a clinical-stage biopharmaceutical company, announced today that data from its pharmacokinetic study of Oral ATO formulation has been accepted for poster presentation at the upcoming 67th American Society of Hematology (ASH) Annual Meeting, to be held December 6–9, 2025, in Orlando, Florida.

The poster, titled: **"Pharmacokinetics and cardiac impact of arsenic trioxide (ATO) oral solution (SDK001) under fasting, fed, and calcium carbonate co-administration conditions compared with intravenous ATO in patients with acute promyelocytic leukemia"** will be presented during the following session:

- **Session:** 604. Molecular Pharmacology and Drug Resistance: Myeloid Neoplasms: Poster I
- **Date:** Saturday, December 6, 2025
- **Time:** 5:30 PM – 7:30 PM (EST)
- **Location:** Orange County Convention Center (OCCC) – West Halls B3-B4
- **Publication Number:** 1506

Study Overview

The randomized, open-label, single-dose, four-period crossover study (SDKARS-101) was conducted in patients with acute promyelocytic leukemia (APL) in remission. The trial compared SDK001 under fasting, fed, and calcium carbonate co-administration conditions with intravenous (IV) ATO.

Results demonstrated that SDK001 achieved systemic arsenic exposure comparable to IV-ATO under fasting conditions, with no effect of food or calcium carbonate on exposure. Moreover, SDK001 was associated with reduced QTc prolongation relative to IV ATO, particularly under fed conditions. These findings support the upcoming global Phase 3 ***LATITUDE*** **trial (SDKARS-301)** evaluating Oral ATO as a potential treatment for APL with reduced patient burden.

"The ASH selection recognizes the growing body of evidence supporting SDK Oral ATO as a practical and potentially safer alternative to intravenous ATO," said **Stéphane Berthier, PharmD, CEO of SDK Therapeutics**. "We are proud to share these important clinical data with the hematology community as we advance our pivotal Phase 3 *LATITUDE* trial."

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.

An oral formulation of ATO was developed as a more patient-centered alternative by the University of Hong Kong. Since receiving regulatory approval in Hong Kong for the treatment of APL, it has been administered to more than 450 patients across both newly diagnosed and relapsed settings. Clinical trial data have demonstrated a favorable long-term safety and efficacy profile. Administered once daily, Oral ATO 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, Oral ATO 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, Oral ATO 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).