



Removing Treatment Burden in Acute Promyelocytic Leukemia

SDK THERAPEUTICS: ENHANCE THE LIFE OF APL PATIENTS

By removing treatment burden and improving safety profile



PROBLEM

Acute Promyelocytic Leukemia (APL) is a subset of Acute Myeloid Leukemia (AML)
IV Arsenic Trioxide (ATO) is standard of care with high cure rate (97% EFS)

BUT:

- IV ATO infusion takes 2 hours & repeated up to 140 times over 10 months
- Burdensome for patients, caregivers, and costly for health care system

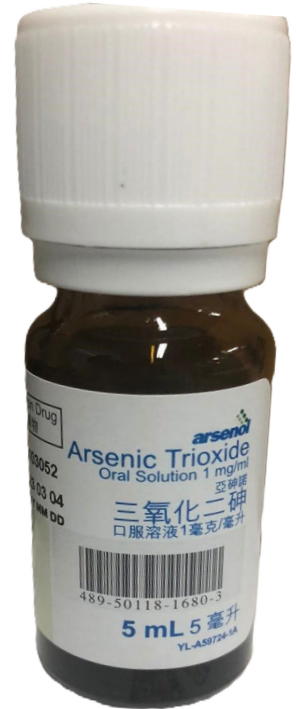
SOLUTION

SDK001: Oral formulation of ATO

- Exclusive license of SDK001 (Oral ATO) for North America & Europe
- Established safety and efficacy in more than 400 APL patients
- Approved in Hong Kong

PROGRESS

- **Regulatory pathway aligned with the FDA** (Pre-IND) and **EMA** (SA)
- **Orphan Drug Designation granted** in both the US and EU
- **IND application cleared by the FDA** in Jan'25
- **PK study fully enrolled** in May'25
- Plan to initiate Phase 3 in Q3 '25, leading to approval by 2028 with global peak year sales of \$1B*



FINANCING: \$35M Series A to register SDK001 in both US and EU

SDK001 WILL ELIMINATE INFUSION BURDEN OF IV ATO

With similar efficacy and potential safety advantage

SDK Tx

APL OVERVIEW

- Subset* of AML (5-10%)
- ~ 2,500 patients (US + EU)
- Young patients (median: 48 y.o.)

APL TREATMENT

- Oral ATRA & IV ATO are Standard of Care



IV ATO



Oral ATRA

- Curative in most patients
- 97% Event-Free Survival at 50 months**

IV ATO TREATMENT BURDEN

- Up to 140 infusions (2-hour)



Over 10 months



- Frequent trips to infusion center
- Inability to go back to work (reduce productivity)
- High healthcare resource utilization

SDK001 (Oral ATO)

Enhance patient experience

Improve Quality of Life

Lower risk of QTc prolongation

Reduce health care resources

Benefits to be validated in randomized study

*: defined by a cytogenetic finding: Translocation t(15;17), with the subsequent creation of a fusion gene, PML/RARA (Promyelocytic leukemia/retinoic acid receptor alpha gene)

**: Platzbecker U et al (2017) Final Results of the Randomized Italian-German APL0406 Trial

QTc: Corrected QT Interval ATRA: All-Trans Retinoic Acid ATO: Arsenic Trioxide.

PROVEN EFFICACY & ESTABLISHED SAFETY WITH SDK001 IN APL

Approved in Hong Kong



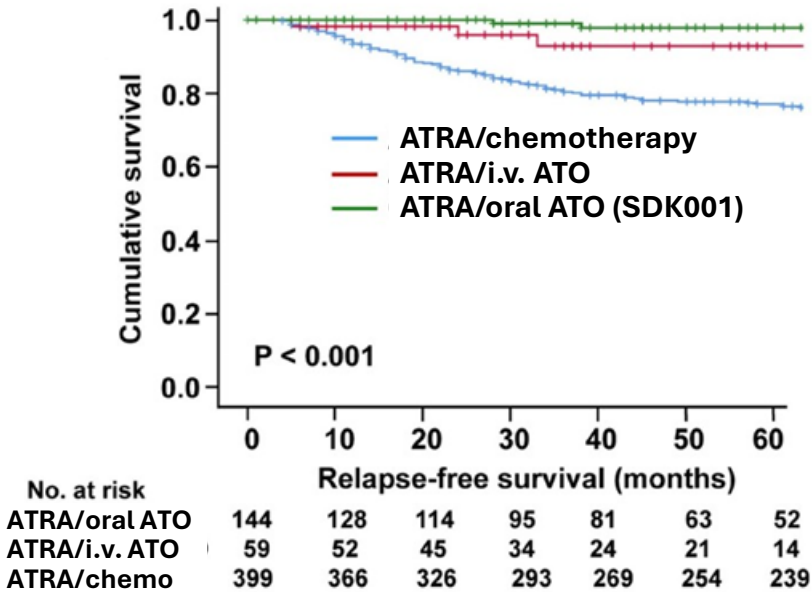
More than 400 APL patients treated with SDK001 with similar plasma AUC exposure vs IV ATO

Strong efficacy of SDK001 in newly diagnosed APL patients with 97% RFS and OS at 3 years*

Potential safety advantage of SDK001 with reduced rate of QTc prolongation & grade 3-4 hepatotoxicity

RELAPSE-FREE SURVIVAL

- SDK001 demonstrated similar efficacy profile as IV ATO**



Gill H et al (2024)

*: Gill H et al (2023) An Entirely Oral Regimen of Oral-ATO / ATRA / Ascorbic Acid in Newly-Diagnosed APL: Updated Results of an Ongoing Multicentre Trial. ASH 2023
**: Gill H et al (2024) Acute Promyelocytic Leukemia Asian Consortium study of arsenic trioxide in newly diagnosed patients: impact and outcome. Blood Advances
RFS: Relapse-free survival OS: Overall Survival

SUPPORT FOR SDK001 FROM APL LEADERS

With the goal to remove IV ATO treatment burden



“A proven oral formulation of ATO that offers similar efficacy while dramatically reducing the treatment burden of frequent intravenous infusion would represent a major advance for APL patients.”

– Jessica Altman, MD, Northwestern University, Chicago, USA
Vice Chair AML NCCN Guidelines

“Oral ATO (SDK001) is the first and only oral formulation of arsenic trioxide extensively tested in APL. ”

– Harry Gill, MD, The University of Hong Kong, Hong Kong SAR



“Oral ATO during consolidation could significantly reduce frequent and prolonged visits of APL patients and caregivers in outpatient clinics and reduce healthcare resource utilization.”

– Maria Teresa Voso, MD, University of Rome Tor Vergata, Rome, Italy

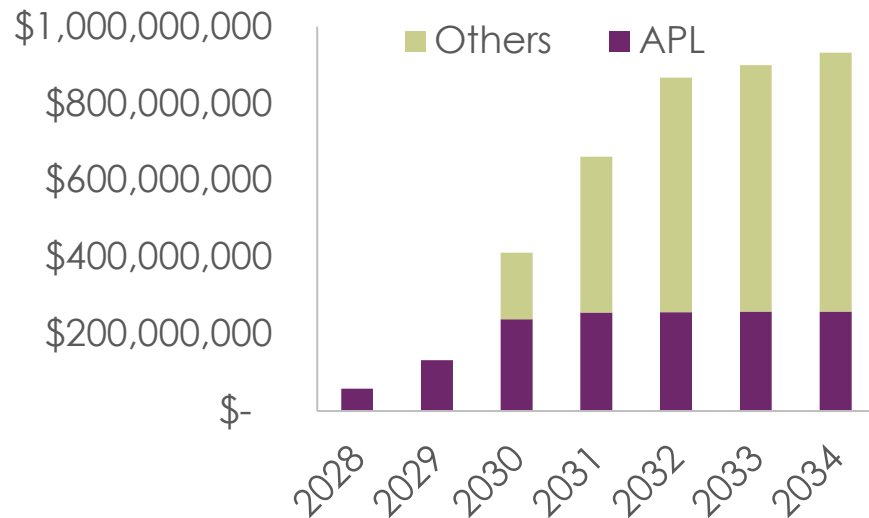
BROAD AND RAPID CONVERSION TO SDK001 WHEN APPROVED



No expected competition and limited promotional efforts required

SALES

- Global peak year sales to reach \$1B including \$250M from APL
- Non-APL indications with preclinical rational are being actively investigated in clinical setting (IITs to be initiated in '25)



DRIVERS

EXCLUSIVITY

- 7- and 10-year orphan drug exclusivity to be granted in US and EU, respectively
- Study in pediatric APL to extend market exclusivity*
- Strengthen protection with new formulation patent

CUSTOMERS

- Strong interest & support from APL physicians to study and use SDK001
- Highly concentrated market as all APL patients are initially treated in large academic centers

*: additional market exclusivity: 6 months in the US, and 2 years in Europe
IIT: Investigator Initiated Trial

SHORT DEVELOPMENT PROGRAM LEADING TO LAUNCH IN EARLY 2028



Aligned with the FDA (Pre-IND)

ACCELERATED PATH TO MARKET



Regulatory pathway leverages:

- 505(b)(2) pathway
- Innovative regulatory strategy
- Long-term efficacy & safety of approved Trisenox® (IV ATO)
- Hong Kong data from more than 400 APL patients treated with SDK001

REGULATORY MILESTONES



US (FDA)

- Pre-IND completed in Oct'24
- ODD granted in Nov'24
- IND application cleared in Jan '25



EU (EMA)

- ODD granted in Dec'24
- Scientific Advice completed in Mar'25



FINANCE: RAISING \$35M TO CONDUCT PHASE 3 STUDY

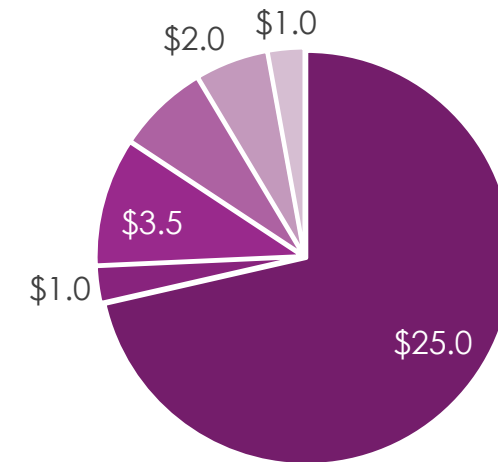
Leading to approval of SDK001 in APL by 2028

CURRENT FINANCIAL SITUATION

- Raised \$2.35M (SAFE & Convertible Notes)

SERIES A ROUND (\$35M)

- Complete phase 3 study in APL
- Register SDK001 in the US and EU by 2028
- Explore new indications
- Seek EU licensee (non-dilutive financing)



- CRO (Phase 3)
- Personnel
- IMP
- Operating cost
- New indications
- Milestone payment

EXPERIENCED LEADERS IN HEMATOLOGY/ONCOLOGY



Stephane Berthier
PharmD, MBA
Founder and
Chief Executive Officer



Danelle James
MD, MS
Chief Medical Officer



Abhijit Pangu
M.Pharm, RAC
Head of Regulatory
Affairs & CMC



BOARD OF DIRECTORS



Scott Dylla
PhD
Director



Benjamin Looker
J.D.
Director



SDK001 ON THE PATH TO BECOME THE NEW STANDARD OF CARE IN APL WITH APPROVAL BY 2028



Experienced team in developing and commercializing assets in Hematology and Oncology



Addressing APL unmet need by substantially reducing treatment burden, health care cost, and improving QOL



De-risking project with proven efficacy and potential safety advantage of an established molecule



Approval within 3 years with \$35M investment to approval from dilutive and non-dilutive financing



Global peak year sales exceeding \$1B, including \$250M from APL