

PINION IMMUNOTHERAPEUTICS

Executive Summary | Series A Financing · PIN-001 (ARV-2001) HPV-16 Therapeutic Vaccine | 10 April 26

Company Overview

Pinion Immunotherapeutics is a clinical-stage mRNA-LNP immunotherapy company based in North Bethesda, MD. Led by CEO Gregory Glenn, MD (former President of R&D at Novavax) Pinion is developing a pipeline of mRNA-based therapeutic vaccines targeting chronic infection-driven diseases and cancers.

Pinion's lead program, PIN-001 (ARV-2001), is a mRNA-LNP therapeutic vaccine for HPV-16+ cervical high-precancers (cHSIL / CIN2/3); FDA-cleared IND as of Jan 2026 and Phase 1/2 initiation planned for Q2–Q3 2026.

The Problem & Market Opportunity (ARV 2001)

- HPV16-driven precancer (cHSIL/CIN2/3) affects hundreds of thousands of US women annually — the cancer precursor at a 9:1 ratio to invasive cervical cancer.
- The current standard of care, LEEP (Loop Electrosurgical Excision Procedure), is performed in ~250,000+ US cases per year and carries recurrence rates ~25%; risks of cervical insufficiency, preterm birth.
- Prior therapeutic HPV vaccine trials (protein, viral vector, DNA) demonstrated proof of concept but fell short of clinical efficacy thresholds. mRNA-LNP technology now provides the potency to cross that threshold.

Scientific Differentiation — ARV-2001

- mRNA-LNP platform encoding HPV-16 E6/E7 antigens, delivered ID for superior CD8+ T cell induction.
- Proprietary combination of an Immune Response Enhancer (IRE) and T-cell Infiltrating Enhancer (TIE) drives tumor-infiltrating lymphocyte expansion and precancer clearance.
- Three decades of therapeutic HPV vaccine science have validated the T-cell mechanism — ARV-2001 applies best-in-class mRNA technology to a de-risked biology.

Pipeline

Program	Indication	Stage	Timeline
PIN-001 (ARV-2001)	HPV-16+ Cervical Precancer (cHSIL/CIN2/3)	Phase I/II	Q3 2026 Start
ARV-1004	EBV: Infectious Mono, MS, Periodontitis	IND Enabling	2026–2027
ARV-1002	HSV: Genital Herpes, Neonatal Herpes	IND Enabling	2026–2027
DCAR-001/002	AML; KRAS-mutant PDAC / Colorectal CA	Discovery	2026–2027

Series A Financing — \$20M

Structure	Two tranches, milestone-gated
Tranche 1 — \$6M	Phase I activation & enrollment (Q3 2026): safety and immunogenicity data
Tranche 2 — \$14M	Phase II efficacy study + IND safety bridging study & FDA interaction (Q4 2026)
Status	Lead investor committed \$6.5M total; seeking \$3M to close Tranche 1
Key Milestones	Phase I safety data Q4 2026 · Phase II efficacy readout Q4 2027

Leadership & Advisors

Leadership Team Gregory Glenn, MD — CEO (IOMAI, Novavax) Jianzhu Chen, PhD — Co-Founder & Board Chair (MIT Koch Institute) Renhuan Xu, PhD — CSO & Co-Founder Regina Jakacki, MD — CMO (AZ, J&J, CHOP)	Strategic Advisors Phil Krause, MD — Regulatory (Former Deputy Director, FDA CBER) Robert Redfield, MD — PHS (Former CDC Director) James Young, PhD — Former President R&D, Medi Richard Douglas, PhD — Corp. Dev; NVAX, Genzyme
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