KOVINA THERAPEUTICS, INC.

Company Overview

Kovina Therapeutics is an early-stage drug discovery company focused on **stopping HPV premalignant infections before cancer develops and treating HPV cancers after detection**. The company's proprietary science includes novel small molecule antiviral compounds which bind to and inactivate a key HPV protein always expressed in early, premalignant, and cancerous pathologies. With $5.1 million in financing, the company assembled a team of experts in HPV and drug development to advance both programs.

Problem or Market Opportunity

Kovina's target US market is ~$4 billion annually across multiple indications including cervical and oropharyngeal (head and neck) cancers and cervical/anal dysplasia. OUS opportunities represent an even larger market with cervical cancer rates equal to 35-40x US rates. Globally, **HPV causes ~5% of all cancers** and nearly 630,000 HPV-related cancers occur each year. In addition, 300,000 US women are diagnosed with HPV16 premalignant cervical infections annually. While the existing HPV vaccine is effective, it has not been widely adopted and has no impact on existing HPV infections or malignancies which develop over years or decades. Competitive therapeutics in development include immunogens and non-specific antivirals that have not been effective in clinical trials. Kovina's compounds are the **only specific antiviral** compounds that induce death of HPV infected cells.

Technical & Competitive Advantage

HPV premalignant infections are currently treated with invasive procedures including lasers, electrocautery, or cryotherapy that may result in serious side effects such as infertility, miscarriage, and cervical stenosis. Kovina's first-in-class therapeutic replaces existing surgical interventions. Treatments for HPV induced malignancies include surgery, radiation, and chemotherapy with high morbidity and challenging side effects. Oropharyngeal cancer patients have the second highest suicide rate among cancer survivors due to serious complications from the current standard of care. Kovina's compounds are designed to specifically kill HPV infected cells and reduce the side effects from intense chemo/radiation and surgical regimens by shrinking tumors prior to resection.

Regulatory Strategy & Intellectual Property

Kovina's intellectual property is protected by a patent portfolio the company co-owns with Indiana University and licensed to secure exclusive rights. Kovina will request a pre-IND meeting in late 2023 to seek regulatory guidance for its first-in-class premalignant infection program. While oncology small molecule regulatory pathways are well defined, the company intends to explore accelerated approval for HPV induced head and neck cancers.

Key Milestones

Q/YYYY	Objective	Milestone Description
Ongoing	**Oropharyngeal cancer program -** preclinical studies to nominate a clinical candidate	ADME characterization, pharmacology and tox studies, GLP Tox and formulation development
Q4 2024	**Oropharyngeal cancer program** - IND filing	Complete IND filing to enter Phase Ib/2 human trials
Ongoing	**Premalignant infection program** – dose range studies, GLP tox and formulation development	Maximum tolerable dose/dose range finding studies underway. Formulation development work scheduled to assess optimal forms for cervical and anal delivery
Q3 2024	**Premalignant infection program** – IND filing	Complete IND filing to enter Phase I/1b human trials

Capitalization History

Year	Grant or Equity Type	Description	Amount
June 2021	Seed round	Local venture funds and angel investors	$2,050,000
March 2022	NCI grant	Fast track grant *(includes ICORPS)* - HPV cancer therapeutics	$2,337,191
July 2022	NIAID grant	Phase I SBIR – HPV premalignant infections	$298,527
Sept 2022	NIDCR grant	Phase I SBIR – HPV oropharyngeal cancers	$275,766
2022	Grants	Elevate Ventures – matching grants	$200,000

Current Round, Terms, and Use of Proceeds

Kovina is initiating financing and partnering efforts to advance its programs to treat HPV induced cancers (oropharyngeal) and HPV premalignant infections (cervical/anal). A $25 million equity round will fund both programs through initial proof of concept studies (Phase 1/1b for cervical/anal dysplasia and Phase 1b/2 for ororpharyngeal cancer) and provide runway through mid-2026.

Key Team Members and Advisors

Kristin Sherman, MBA | Chief Executive Officer

Leads the organization with 30 years of broad experience in drug and device development including large pharma (Eli Lilly), medical devices, and CFO roles in three prior biotech start-up companies, two with successful exits to Roche and Novo Nordisk.

Elliot Androphy M.D. | Chief Scientific Officer and Co-founder

Directs all research efforts leveraging background as a practicing dermatologist, HPV key opinion leader, former department chair and active researcher at Indiana University. Dr. Androphy's labs have received continuous NIH and other grant funding for 35 years to conduct HPV research.

W. Garrett Nichols, M.D., M.Sc. | Chief Medical Officer

Responsible for clinical strategy and oversight. Dr. Nichols led multiple antiviral programs for Glaxo Smith Kline and ViiV Healthcare resulting in approval of dolutegravir for HIV. Dr. Nichols also served as CMO for Chimerix (antivirals) and Istari Oncology (immunotherapeutics for solid tumors.)

Paddy Shivanand M.S., Ph.D. | VP Preclinical Development and CMC

Leads preclinical development leveraging more than 20 years of development experience with Alza Corporation, Johnson & Johnson and various biotech companies. During her career, Dr. Shivianand has advanced more than 25 molecules through various routes of administration.

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