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 science includes novel small molecule antiviral compounds that kill HPV infected cells by binding to and inactivating HPV-16 E6, a key HPV protein always expressed in early, premalignant, and cancerous pathologies.

Market & Commercialization Strategy

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 with limited success in clinical trials. Kovina's compounds are the **only specific antiviral** compounds that induce death of HPV16 infected cells.

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 cancers include surgery, radiation, and chemotherapy with high morbidity and challenging side effects. Oropharyngeal (head/neck) 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 an INTERACT meeting in 2024 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	**Cervical/Oropharyngeal cancer program –** lead candidate screening and preclinical studies to nominate a clinical candidate	ADME characterization, formulation development, pharmacology/tox studies and GLP Tox (funding dependent)
Q2 2026	**Cervical/Oropharyngeal cancer program** - IND filing	Complete IND filing to enter Phase Ib/2 human trials (funding dependent)
Q1 2026	**Premalignant infection program** – dose range studies, GLP tox and formulation development	Maximum tolerable dose/dose range finding studies. Formulation development work scheduled to assess optimal forms for cervical delivery (funding dependent)
Q2 2026	**Premalignant infection program** – IND filing	Complete IND filing to enter Phase I/1b human trials (funding dependent)

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	$2,340,000
July 2022	NIAID grant	Phase I SBIR – HPV premalignant infections	$299,000
Sept 2022	NIDCR grant	Phase I SBIR – HPV oropharyngeal cancers	$276,000
2022	Grants/Convertible note	Elevate Ventures – matching grants ($200k) and convertible note ($75k)	$275,000
2024	Convertible Note	American Cancer Society investment matched by Elevate Ventures	$200,000

Use of Proceeds

Kovina is raising a $20 million Series A round to fund its oncology program through Phase I/II clinical trials in oropharyngeal cancer.

Key Team Members

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 (Guidant Corporation), 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 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. Shivanand has advanced more than 25 molecules through various routes of administration.

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