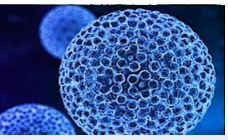
Innovene THERAPEUTICS

INV-015



PREVENTING CANCER BEFORE IT BEGINS - THE FIRST DIRECT ANTIVIRAL FOR HPV

Executive Summary

Vision Statement: Our mission is to eliminate the physical, emotional, and societal burdens of HPV-driven diseases by developing first-in-class antiviral therapies. We are committed to providing non-invasive, patient-friendly treatments that empower patients to lead healthier, anxiety-free lives while reducing the financial strain on healthcare systems.

Background While most HPV infections are transient, a significant number become persistent leading to cancer. HPV is the primary cause of cervical carcinoma. CDC estimates **21.71 million have a high-risk cancer causing cervical HPV** with 5.4 million cases added annually in the U.S., this causing to **200,000 cervical pre-cancers** each year. Yet, no cure exists, and clinicians can only *"watch and wait"* until a precancerous lesions develop, leaving surgery or ablation as the only invasive options which carry risks for future pregnancies.

HPV is not just a women's health issue—it causes a broad spectrum of diseases in both men and women, contributing to significant morbidity and mortality.

- **25% of U.S. men** carry untreatable, cancer-causing HPV infections, serving as a major transmission source.
- Oncogenic HPV strains drive head and neck, anal, vaginal, and penile cancers.
- Non-oncogenic strains cause painful, persistent genital & skinwarts, impacting quality of life.

Despite the availability of vaccines, millions of individuals remain susceptible to these HPV-driven conditions. There is an urgent need to transform the standard of care, by eliminating infections before they progress.

Current Focus & Indication: Our immediate priority is to develop effective treatments for persistent cervical HPV infections, addressing a critical gap in women's healthcare.

Long-Term Vision & Indications: Beyond cervical HPV infections, our goal is to prevent HPV-driven head and neck cancers, treat anal and penile HPV infections and related cancers, and target genital & skin warts and other HPV-associated conditions. Through continuous innovation, we aim to expand our impact and redefine the of care for HPV-related diseases.

Scientific/Technological Platform Innovene has made a pioneering advancement in drug development by successfully targeting the **HPV's oncogenic E6 & E7 proteins**—long considered undruggable despite their pivotal roles in viral replication and cancer progression

Our discovery platform identified unique structural chemical motifs (shapes) with potent antiviral activity through cell-based screening. These selected compounds form the foundation for combinatorial drug testing, using a proprietary set of HPV positive cell lines to develop pharmaceutical mixtures. These formulations are further refined and validated in specialized papillomavirus animal models.

Our mixtures showing broad antiviral activity across multiple HPV genotypes and the *Papillomaviridae* family. This approach led to the development of our lead formulation, **INV-015,** which has been independently validated through the NIAID/NIH In Vivo Drug Testing Program, both in the mouse papillomavirus (MmuPV1) model and rabbit papillomavirus (CRPV) model.

This unprecedented success across multiple models underscores INV-015's potential as a first-in-class, non-invasive therapeutic. With a dual mechanism of action—direct inhibition of papillomavirus oncogenic proteins (E6/E7) and immune system reactivation—INV-015 is positioned to transform how HPV infected diseases are treated and managed.

Flagship Product Topical INV-015, is a self-administered, topical antiviral designed to treat cervical HPV infections before they progress to cancer. It features a patent-protected self-emulsifying delivery system that enhances drug stability and forms a micro-emulsion upon contact with vaginal moisture. This unique feature improves adherence, prolongs contact with mucosal surfaces, and enhances drug penetration, effectively targeting HPV-infected cells. Designed for easy self-application—similar to common intravaginal treatments for yeast infections—INV-015 offers an accessible, cost-effective solution, making it ideal for self-administration and global health applications

Regulatory Pathway Innovene is advancing INV-015 through a well-defined FDA approval pathway with the goal of achieving first-in-class status. We have completed GLP IV toxicity studies in rats to determine the Maximum Tolerated Dose (MTD) and are preparing for intravaginal GLP toxicity studies in rabbits to assess safety and pharmacokinetics (PK). These studies will generate important dosing and safety data to inform Phase 1 clinical trial design.

Our next regulatory milestone is a Pre-IND meeting with the FDA, where we will align on requirements, finalize IND-enabling studies, and prepare for submission. We aim to leverage the FDA's Fast Track designation to accelerate approval and streamline development timelines.

Following IND approval, we will initiate Phase 1 trials, setting the stage for later-phase studies and eventual commercialization. With patent protection and a strong regulatory strategy, Innovene is positioned to maximize market exclusivity and secure early-mover advantage in the HPV therapeutics landscape.

Market Differentiation Despite the HPV vaccines being available, the US spends approximately **$9 billion annually on direct medical costs** related to HPV-driven diseases, according to a CDC study (Claya, PA et al., Vaccine, 2023). This significant economic burden highlights a substantial market opportunity for our innovative antiviral therapy. By eliminating HPV infections at the source, our antiviral has the potential to drastically reduce healthcare costs, improve patient outcomes, and transform the standard of care. Addressing the root cause of HPV-related diseases not only delivers clinical and economic benefits but also represents a paradigm shift in HPV treatment.

Competitive Landscape There is growing interest in treating persistent HPV infections, with companies such as Kovina Therapeutics, Barinthus Bio, KinoPharma, and Frantz Viral Therapeutics developing therapies aimed at HPV-driven diseases, including precancerous lesions and cancers. However, no approved treatments exist for high-risk cancer causing HPV infections.

Innovene stands apart as the sole company with independent validation through the NIAID In Vivo Efficacy Program for anti-HPV drugs and as a pioneer in directly targeting the key oncogenic proteins, E6 and E7—critical drivers of HPV infection and cancer progression. Unlike vaccines, which prevent new infections but cannot treat existing ones, Innovene directly addresses the treatment gap. While HPV vaccination remains an essential tool in prevention, its limitations—including the inability to treat pre-existing infections—highlight the need for complementary therapeutic strategies like INV-015. By eliminating HPV infections and integrating antiviral treatment with prevention, Innovene's approach supports broader HPV eradication goals, ultimately transforming how HPV is managed on a global scale.

Partnership Opportunities Recognizing that effective treatment extends beyond the active drug, our collaboration with PCCA (Houston, TX) enhances our drug discovery and focuses on developing patient compatible formulations with optimized delivery vehicles to enhance stability, permeability, and shelf life. PCCA collaborates with Innovene with scientific and regulatory expertise, R&D facilities, and scientific support , allowing us to conduct critical drug optimization and formulation experiments at their laboratories.

With cGMP-compliant manufacturing operations, PCCA ensures that our therapeutics meet the highest standards of quality and regulatory compliance. PCCA's collaboration strengthens our mission, reinforcing a shared commitment to delivering transformative antiviral therapies with scalable, high-quality production.

Team Innovene's leadership team combines scientific expertise and business acumen to drive innovation. The co-founders bring deep expertise in virology, immunology, strategic planning and startup experience in challenging. Together, they lead a team dedicated to developing transformative antiviral therapies and navigating complex regulatory pathways with precision to reach the clinical setting.

Exit Strategy/Pharma Partnership We anticipate licensing opportunities or acquisition by larger pharma companies, potentially as early as Phase 1, if the study confirms an early-stage antiviral efficacy endpoint. This timeline could accelerate our therapeutic's efficacy, aligning with market consolidation trends and the growing clinical demand for HPV treatments.

Social/Global Impact Our drug candidate addresses significant health inequities by offering an affordable, self-administered treatment for persistent HPV infections, particularly benefiting low- and middle-income countries where healthcare infrastructure is limited. In China, despite the introduction of the HPV vaccine in 2016, national vaccination rates remain low, with only 10.15% of females aged 9–45 having received at least one dose by 2022. Similarly, in many African nations, HPV vaccination coverage is alarmingly low, contributing to higher rates of cervical cancer. In Latin America, vaccination rates have improved, reaching about 48% in 2023, yet still leaving a significant portion of the population unprotected. Our low-cost, self-administered therapy is designed to overcome these barriers, providing effective treatment options in regions with limited access to healthcare services.

Intellectual Property (IP) In 2024, Innovene filed a Patent Cooperation Treaty (PCT) application covering novel pharmaceutical combinations along with a proprietary drug delivery system to establish broad global protection for its antiviral platform. This early-stage patent filing extends the potential for long-term market exclusivity, providing a strong intellectual property foundation as we progress through clinical development and commercialization. Beyond the PCT, Innovene is actively conducting R&D to expand activity of drug formulations, delivery mechanisms, and potential pipeline innovations, further reinforcing our IP position in the antiviral therapeutics space.

Use of Funds To date, Innovene has effectively utilized a combination of internal and external resources to advance our drug candidate Internal Funding: raised through personal investments and contributions from friends and family. PCCA Contribution: $1 million preclinical drug develop and testing, and allocated for the filing of patent, underscoring their commitment as a valued scientific collaborator and business partner.

NIAID Support: The National Institute of Allergy and Infectious Diseases (NIAID) has sponsored critical preclinical studies, including:

- Cottontail Rabbit Papillomavirus (CRPV) Study: Estimated at approximately $200,000.
- Mouse Papillomavirus (MmuPV1) Study: Estimated at approximately $150,000.
- Intravenous (IV) Maximum Tolerated Dose (MTD) Study in Rats: Estimated at approximately $110,000. These NIAID-sponsored studies, conducted by subcontractors, represent an estimated in-kind contribution of $450,000.

Note: The cost estimates for the preclinical studies are based on typical contract research organization (CRO) rates for similar studies, as specific figures were not disclosed by NIAID.

Funding Strategy & Cost Estimate to through Phase 1 Clinical Trial

Innovene is seeking $1 million to complete IND-enabling studies, conduct Pre-IND meetings, and submit the IND application for INV-015, paving the way for Phase 1 clinical trials. This funding requirement is significantly lower than industry norms. Typically, small-molecule formulation development and testing can cost $1.5–$2 million, but PCCA's investment and expertise in formulation testing and manufacturing has substantially reduced these expenses. Additionally, the independent validation of INV-015 by the NIAID In Vivo Drug Testing Program serves as a key de-risking milestone, strengthening the scientific foundation of the program and supporting regulatory positioning, demonstrating its potential for further clinical development.

Beyond the IND submission, Phase 1 clinical trials will require additional funding, with costs influenced by regulatory feedback and manufacturing scale-up. To optimize resources and maximize capital efficiency, Innovene is implementing a multi-pronged funding strategy:

- Non-Dilutive Funding: Continuing to pursue SBIR and NIH funding to offset preclinical and early clinical trial costs, reducing reliance on equity financing.

- Strategic Partnerships: Leveraging PCCA's formulation, manufacturing, and regulatory expertise to lower upfront costs. We will propose to the FDA that the study drug (Topical INV-015) be manufactured at PCCA under cGMP-compliant conditions, representing a significant cost-saving opportunity if approved.

- Efficient Trial Design: Structuring the Phase 1 clinical trial with secondary efficacy endpoints to assess early virologic activity, providing critical biological proof-of-concept in humans. This approach helps mitigate early-stage risk and establishes key investment milestones to attract potential pharmaceutical partnerships.

Total Funding Required to Complete & file an IND & Conduct Phase 1: $4M–$5.2M
Securing this funding will allow INV-015 to efficiently progress through Phase 1 trials, positioning it as a first-in-class therapeutic for HPV infections while ensuring a strategic, cost-effective, and investor-aligned path to market.

Call to Action

Innovene harnesses the wisdom of millions of years of nature's chemical evolution and combines it with the precision of cutting-edge science. By bridging the ancient and the modern, we are creating innovative therapies that address HPV infections and transform the future of antiviral care. More than a treatment—it's a testament to what is possible when nature and science work in harmony.