EG-HPV: Human papillomavirus vaccine based on Virus-Like Particle (VLP) technology (HPV 16 & 18 L1 VLP) and a novel proprietary immune adjuvant EGvac (adjuvant system CIA05+alum) that enhances the immune response against HPV through both B cell (humoral) and T cell (cellular) immune stimulation

EyeGene Inc.

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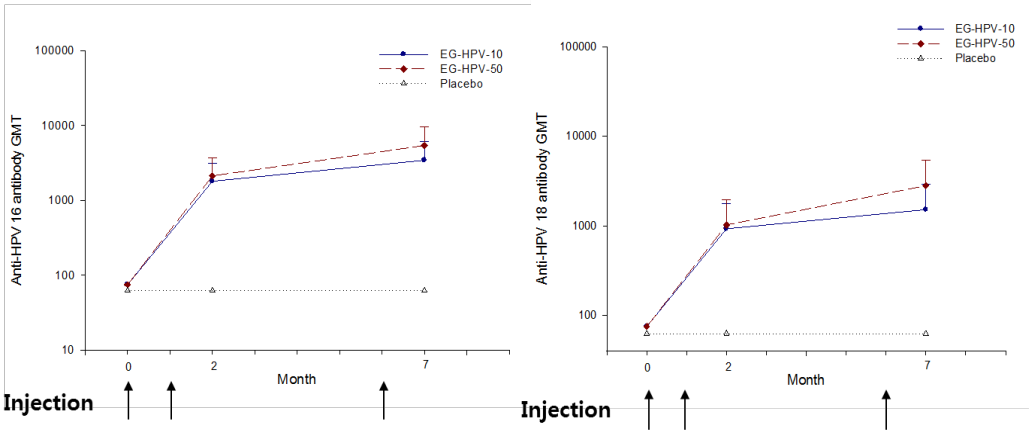
Industry Sector	Biotecnology
Therapeutic Area	Oncology, Other therapeutic
Stage of Development	Phase I

1. Summary

- EG-HPV is a combination between Virus-Like Particle (VLP) technology (HPV 16 & 18 L1 VLP) and a novel proprietary immune adjuvant EGvac (adjuvant system CIA05 + alum) that enhances the immune response against HPV through both B cell (humoral) and T cell (cellular) immune stimulation.
- Preclinical efficacy and toxicity studies have been completed with manufacturing processes established.
- Phase I clinical trials conducted at Seoul National University Hospital have also been successfully completed. Primary endpoints included safety & tolerance evaluation, and immunogenicity evaluation (anti-HPV 16/18 L1 IgG titer measurements and neutralizing anti-HPV 16/18 L1 titer measurements).



HPV16/18 L1 VLP-specific serum total IgG antibody titers (Source: Phase I Clinical studies; Seoul National University Hospital)
(1) EG-HPV-10 (HPV 16 antigen 20μg, HPV 18 antigen 20 μg, CIA05 10μg, alhydrogel®),
(2) EG-HPV-50 (HPV 16 antigen 20 μg, HPV 18 antigen 20 μg, CIA05 50 μg, alhydrogel®)
(3) Placebo: CIA06 (CIA05 10 μg, alhydrogel®)

2. Applications

Potential applications for novel proprietary immune adjuvant technology EGvac

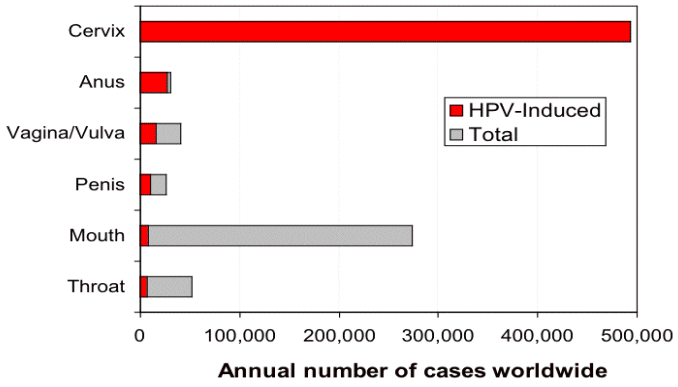
Adjuvant System	Composition	Target Disease
CIA02	TLR9 agonist	-
CIA05	TLR4 agonist	-
CIA06	CIA05 + Aluminum hydroxide	HPV, HBV, anthrax, influenza TB, VZV, *P. aeruginosa*

CIA07	CIA02 + CIA05	cancer immunotherapy
CIA08	CIA05 + Liposome A	TB, VZV
CIA09	CIA05 + Liposome B	TB, VZV, *P. aeruginosa*

3. Market Feasibility

Cervical Cancer Overview

- Human papillomavirus (HPV) infection causes more than 90% of cervical cancer cases
- Over 99% of HPV DNA found in 1,000 tissue samples from cervical cancer patients in 22 countries
- Worldwide, 630 million are estimated to be infected with HPV, which is responsible for the development of nearly all cases of Cervical Cancer.
- By age 50, more than 80% of females are likely to be infected with HPV
- Infection can be prevented with vaccination



Global HPV Vaccine Market

- Global sales(2012) : Gardasil®(Merck) $1.6bn, Cervarix™(GSK) $0.4bn
- Global HPV vaccine market is estimated to reach $3.5bn by 2020 on increased use of Gardasil® and Cervarix™

4. Type of Business Relationship Sought (include licensing availability)

- Available for out-licensing
- Seeking co-development, Strategic partnerships

5. Technical Advantages

- Competitive in terms of both *efficacy* and *cost* versus currently available HPV vaccines.
- Well tolerated in all subjects with strong humoral and cellular immune stimulation in Phase I studies.
- Phase 2 studies are currently being designed in collaboration with domestic partner.

6. Technical Highlighted Summary

- EG-HPV is cost competitive versus both ***Gardasil® (Merck)*** and ***Cervarix™ (GSK)***.
- Gardasil contains 3 times the amount of HPV L1 VLP antigens (120 ug) vs. EG-HPV (40 ug), and also half of the HPV L1 VLP antigens (60 ug) are for HPV 6,11 which are associated with genital warts NOT cervical cancer.
- EG-HPV is cost effective versus ***Cervarix™*** due to the process of manufacturing.

EG-HPV – Comparison with Currently Marketed Vaccines

	Gardasil® (Merck)	***Cervarix™ (GSK)***	**EG-HPV**
Contents	HPV 6 L1 VLP (20 ug), HPV 11 (40 ug), HPV 16 (40 ug), HPV 18 (20 ug) + aluminum (225 ug)	HPV 16 L1 VLP (20 ug), HPV 18 L1 VLP (20 ug) + aluminum (500 ug) + MPL (50 ug)	HPV 16 L1 VLP (20 ug), HPV 18 L1 VLP (20 ug) + aluminum (500 ug) + dLOS *(CIA05)* (10 ug)
Production host	Yeast	Insect cell	Yeast
Injection schedule	3 times (0, 2, 6) 2 times (9~13years)	3 times (0, 1, 6) 2 times (8~13years)	3 times (0, 1, 6)
Immune Adjuvant	Aluminum hydroxyphosphate sulfate	MPL and aluminum hydroxide (AS04)	dLOS (CIA05) and aluminum hydroxide

7. Patent Information and Status

EyeGene has more than 45 issued and 24 pending patents globally including US, EU, Japan and China.
EyeGene secured comprehensive intellectual property for EG-HPV.

8. Patent Number(s)

Title	Country	Patent Application No.	Original Assignee	Filing Date	Inventors
Vaccines for cervical cancer	PCT	PCT/KR2009/006062	EyeGene Inc.	2007.01.19	Hong-Jin Kim et al.
	Korea	10-2009-0099982		2009.10.20	
		10-2011-0137242		2011.12.19	
		10-2012-0076878		2012.07.13	
	China	200980111082.4		2010.09.27	
	EU	09 846 240.1		2011.11.23	
	AUSTRALIA	2009348078		2011.11.24	
	INDIA	8912/CHENP/2011		2011.12.01	
	JAPAN	2012-515957		2011.12.09	
	INDONESIA	WO.00.2011.04624		2011.12.16	
	MEXICO	MX/a/2011/0013566		2011.12.14	
	BRAZIL	PI0924981-8		2011.12.16	
	CHILE	2011-3206		2011.12.16	
	US	13/379,212		2011.12.19	

9. Key Words

HPV, Human papillomavirus, Cervical cancer, Vaccine, EG-HPV, Adjuvant, VLP, Virus-Like Particle, HPV 16, HPV 18, dLOS, CIA05

10. Company Description

EyeGene Inc. is clinical stage proteomics & bio-pharmaceutical venture based in South Korea dedicated to developing therapeutics, diagnostics, and technologies in eye-related diseases & vaccines.

Since incorporation in 2000, we have focused on the development of new therapeutics and diagnostics for eye-related diseases such as Diabetic Retinopathy (DR) and Retinopathy of Prematurity (ROP). In this respect, we currently have a First in Class novel candidate for Non-Proliferative Diabetic Retinopathy in European Phase 2a clinical trials. In addition, we have a pool of vaccines under development with our novel proprietary immune adjuvant, of which our HPV vaccine is currently in clinical trials.