



TECHNOLOGY LICENSING OFFICE

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BV 2014-01 - *Human Papillomavirus Therapeutic Vaccine*

APPLICATION: Therapeutic vaccine for HPV infections

KEY BENEFITS:

- Therapeutic vaccine for HPV-related cancers
- Induces cell-mediated immune response

MARKET SUMMARY: Cervical cancer is the fourth most common cancer in women worldwide, with an annual incidence of 528,000 cases and mortality of 266,000 cases, and it is almost always caused by human papillomavirus (HPV). HPV causes not only cervical cancer but also anal, oropharyngeal, penile, vaginal, and vulvar cancers; it is estimated to be responsible for 5.2% of cancer cases worldwide. Although numerous preclinical and clinical trials have evaluated prophylactic HPV vaccines during the past few decades, these vaccines do not help those who already have established HPV infections. Therefore, therapeutic vaccines are needed for patients in which HPV infection is already established and in which HPV-related diseases have already developed.

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**TECHNICAL
SUMMARY:**

We have developed an HPV therapeutic vaccine—PepCan—that consists of four synthetic peptides covering the E6 protein of HPV type 16 (HPV 16), along with a Candida skin-test reagent as a novel vaccine adjuvant. This combination is designed to boost anti-HPV E6 responses, which have been associated with HPV clearance and regression of cervical lesions. The four peptides were chosen to keep the most immunogenic regions intact. These four peptides have also been shown to have maturation effects on Langerhans cells (LCs), the main antigen-presenting cells in skin. The most widely used adjuvant in approved human vaccines is an alum-based adjuvant that elicits a predominantly Th2 immune response. However, the alum-based adjuvant would not be useful in a vaccine designed to stimulate cellular immune responses. Because successful clearance of HPV infection is believed to be induced by cell-mediated immunity, an adjuvant that would promote such immunity is necessary. The adjuvant chosen for PepCan is Candin, a colorless extract of *Candida albicans* that functions as a recall antigen. We have demonstrated that Candin has T-cell proliferative effects and that the cytokine most frequently produced by Langerhans cells (LCs) exposed to Candin, with and without vaccine peptides, was interleukin (IL)-12, which promotes T-cell response.

**DEVELOPMENTAL
STAGE:**

Successful Phase I clinical trial in humans

**PATENT
INFORMATION
AND CONTACT:**

App Type: PCT
Country: US
Serial No.: PCT/US2014/060198
File Date: 10/11/2014

App Type: US Nat
Country: US
Serial No.: 15/028,760
File Date: 04/12/2016

App Type: AU Nat
Country: AU
Serial No.: 2014331654
File Date: 03/30/2016

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App Type: CA Nat
Country: CA
Serial No.: 2,927,126
File Date: 03/30/2016

App Type: EU Nat
Country: EU
Serial No.: 14853002.5
File Date: 03/30/2016

App Type: KR Nat
Country: KR
Serial No.: 10-2016-7011884
File Date: 03/30/2016

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