AGONIST EPITOPES FOR THE DEVELOPMENT OF A HUMAN PAPILLOMAVIRUS (HPV) THERAPEUTIC VACCINE

SUMMARY (1024-CHARACTER LIMIT)

To date, there is no FDA-approved therapeutic vaccine for human papillomavirus (HPV). Researchers at the National Cancer Institute (NCI) have discovered agonist epitopes for the development of an HPV therapeutic vaccine. NCI is seeking parties interested in licensing and/or co-developing HPV agonist epitopes that enhance the activation of cytotoxic T lymphocytes (CTL) and lysis of human tumor cells.

NIH REFERENCE NUMBER

E-169-2016

PRODUCT TYPE

- Therapeutics

KEYWORDS

- Human Papillomavirus, HPV, Agonist Epitope, Therapeutic Vaccine, Cytotoxic T Lymphocytes, CTL, Schlom

COLLABORATION OPPORTUNITY

This invention is available for licensing and co-development.

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STATUS

Active

DESCRIPTION OF TECHNOLOGY

Human papillomavirus (HPV) has been associated with the cause of several cancer types, including cervical, anal, and head and neck cancers. There has been great success in preventing HPV infections with the development of prophylactic HPV vaccines, Gardasil and Cervarix. However, these vaccines have only been shown to prevent HPV infection and not treat those already infected with HPV. These vaccines elicit antibody responses to late HPV genes, and thus would not be effective in treating established tumors. To date, no therapeutic HPV vaccine has been approved by the FDA, and there is an

unmet need for therapeutic vaccines for the treatment of cervical, anal, and head and neck cancers.

One approach in the development of HPV therapeutic vaccines is the use of agonist epitopes that would elicit enhanced cytotoxic T-lymphocyte (CTL) responses capable of lysing human tumor cells expressing native HPV epitopes. Researchers at the National Cancer Institute (NCI) have identified three agonist epitopes that target early HPV genes responsible for maintaining the malignant phenotype. Moreover, these agonist epitopes generate CTLs capable of lysing carcinoma cells expressing the native HPV epitope.

The NCI, Center for Cancer Research, is seeking statements of capability or interest from parties interested in licensing and/or collaborative research to further develop, evaluate, or commercialize the HPV agonist epitopes for the development of a therapeutic vaccine.

POTENTIAL COMMERCIAL APPLICATIONS

- Development of HPV therapeutic vaccines for the treatment of cervical, anal, and head and neck cancers
- For cancer immunotherapy targeting HPV-mediated cancers or use as a combination therapy with immune checkpoint inhibitors, other immune modulators and/or chemotherapy, radiation therapy, and other modes of therapy such as the use of small molecule-targeted therapeutics

COMPETITIVE ADVANTAGES

- Gardasil and Cervarix are prophylactic HPV vaccines and are not used to treat HPV-infected individuals. This technology could be used to develop the first therapeutic vaccine for HPV
- HPV agonist epitopes target early HPV genes that are responsible for maintenance of the malignant phenotype. Gardasil and Cervarix target late genes and would not be effective in treating established tumors
- HPV agonist epitopes activate HPV-specific CTLs that lyse tumor cells and control tumor growth/rejection

INVENTOR(S)

Jeffrey Schlom (NCI), Kwong Yok Tsang (NCI)

DEVELOPMENT STAGE

- Pre-clinical (in vivo)

PUBLICATIONS

Tsang KY, et al. Identification and characterization of enhancer agonist human cytotoxic T-cell epitopes of the human papillomavirus type 16 (HPV16) E6/E7. [PMID 28389098]

PATENT STATUS

- **U.S. Provisional:** U.S. Provisional Patent Application Number 62/497,064 , Filed 07 Nov 2016

- **U.S. Patent Filed:** U.S. Patent Application Number PCT/US2017/06010 , Filed 06 Nov 2017

RELATED TECHNOLOGIES

- E-001-2012 - MUC-1 Tumor Antigen Agonist Epitopes for Enhancing T-cell Responses to Human Tumors

THERAPEUTIC AREA

- Cancer/Neoplasm