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Multivalent emergency vaccine against pandemic influenza

Project Number	Contact PI/Project Leader	Awardee Organization
5R43AI136220-02	PUSHKO, PETER M	MEDIGEN, INC.

Description

Abstract Text

ABSTRACT A safe and effective vaccine providing protection from many subtypes of influenza would considerably improve public health and **pandemic** preparedness. Multiple potentially **pandemic** viruses continue to circulate and evolve in the environment causing public health concern. Preparation of vaccines for each subtype using current technologies is not cost-effective and can raise safety and biosecurity concerns if highly pathogenic strains are used. Recombinant virus-like particles (VLPs) represent an intrinsically safe vaccination approach. Influenza VLPs contain viral hemagglutinin (HA), neuraminidase (NA) and matrix or gag proteins, which self-assemble into VLPs in cell culture. VLPs morphologically and antigenically resemble influenza virions except they are non-infectious. Recombinant VLPs have advantages in safety, efficacy, and manufacturing and they circumvent problems like slow virus growth, unpredictable yields, and virus mutations during egg adaptation. In preliminary studies, we described a novel multi-subtype VLP design that co-localizes multiple HA subtypes within the same VLP particle [1, 2]. VLP that contained HA proteins from four distinct avian influenza subtypes H5, H7, H9, and H10 proteins induced specific immune responses against all four subtypes. Therefore, multi-subtype VLP design suggests the potential for a broadly protective vaccine that provides specific immunity against multiple influenza viruses of **pandemic** concern. In this Phase I SBIR application, we propose feasibility study of a novel multivalent vaccine containing HA molecules from all seven zoonotic **pandemic** threat subtypes known to infect humans including these of avian and swine origin. In Sp. Aim 1, VLP vaccines will be prepared in the mono- and multi-subtype formats and optimized for expression of H1, H2, H3, H5, H7, H9, and H10 antigens. VLPs will be expressed using a baculovirus expression system and their structural, antigenic, and biochemical characteristics will be evaluated. The content and the potency of each HA subtype will be measured to determine optimal formulation of VLPs. In Sp. Aim 2, safety, immunogenicity and efficacy of the best VLP formulation will be assessed in experimental ferret model in collaboration with the Centers for Disease Control and Prevention (CDC). Ferrets will be vaccinated with the optimized multivalent vaccine from Sp. Aim 1. Immune responses to the expressed avian and swine HA subtypes will be determined including hemagglutination inhibition (HI) and virus neutralization (VN) titers. In addition, antibodies to NA, as well as IFNγ responses after VLP immunization will also be determined. Vaccine efficacy will be evaluated using challenge with at least two homologous viruses. Additional homologous and heterologous challenge experiments are planned for the follow-up Phase II SBIR if approved by the Agency. If successful, this high-risk, high-reward approach can potentially result in a novel emergency vaccine protecting against multiple potentially **pandemic** viruses known to infect humans.

Public Health Relevance Statement

PROJECT NARRATIVE Preparation of vaccines capable of protecting against multiple potentially pandemic influenza viruses is important for public health. The focus of this Phase I SBIR application is feasibility study of a novel, broadly protective virus-like particle (VLP) vaccine against pandemic influenza viruses of H1, H2, H3, H5, H7, H9, and H10 subtypes, all known to cause life-threatening human infections. Evaluation of safety, immunogenicity and efficacy of vaccine is proposed in ferrets in collaboration with the Centers for Disease Control and Prevention (CDC) including influenza virus challenges. The proposed research of multi-subtype VLPs will increase knowledge of multivalent vaccines and contribute to the development of improved influenza vaccines.

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Contact PI/Project Leader
PUSHKO, PETER M

Awardee Organization
MEDIGEN, INC.

Project Terms

Adverse effects Affect Antibodies Antigens Avian Influenza Back Baculovirus Expression System Biochemical Birds Caliber Cell Culture Techniques Centers for Disease Control and Prevention (U.S.) Cessation of life Characteristics Collaborations Cultured Cells Development Elderly Emergency Situation Environment Evaluation Family suidae Feasibility Studies Ferrets Formulation Future Growth Health Hemagglutination Hemagglutinin Human Immune response Immunity Immunization Individual Infection Influenza

Read More

Details

Contact PI/ Project Leader

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Organization

Name
MEDIGEN, INC.

City
FREDERICK

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Domestic For-Profits

State Code
MD

Congressional District
06

Other Information

FOA
PA-17-302

Study Section
Special Emphasis Panel[ZRG1-IMM-R(12)B]

Fiscal Year
2019

Award Notice Date
04-March-2019

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
167037477

CFDA Code
855

Project Start Date
11-April-2018

Project End Date
31-March-2020

Budget Start Date
01-April-2019

Budget End Date
31-March-2020

Project Funding Information for 2019

Total Funding
$95,379

Direct Costs
$0

Indirect Costs
$0

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Funding IC	FY Total Cost by IC	Category
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$95,379	Biodefense; Biotechnology; Emerging Infectious Diseases; Immunization; Infectious Diseases; Influenza; Pneumonia & Influenza; Prevention; Vaccine Related;

Sub Projects

No Sub Projects information available for 5R43AI136220-02

Publications

No Publications available for 5R43AI136220-02

Patents

No Patents information available for 5R43AI136220-02

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 5R43AI136220-02

Clinical Studies

No Clinical Studies information available for 5R43AI136220-02

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No Historical information available for 5R43AI136220-02

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