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Development of a Yellow Fever Vaccine for a Vulnerable Population

Project Number
5R44AI079898-07

Contact PI/Project Leader
AMANNA, IAN JAMESOther PIs

Awardee Organization
NAJIT TECHNOLOGIES, INC.

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Description

Abstract Text

ABSTRACT Yellow fever **virus** (YFV) represents a mosquito-borne emerging/re-emerging human pathogen that causes 20-50% mortality and is endemic in >40 countries. The current live attenuated YFV vaccine was developed in 1936 and following the establishment of a **virus** seed lot system, it has not been modified or otherwise improved in over 50 years. According to the CDC, this vaccine causes 47 serious adverse events (SAE) per million vaccinations (SAE defined as resulting in hospitalization, long-term disability, or death). Some reports indicate that vaccine-associated neurological disease may occur at a rate of up to 1 case per 10,000 vaccinations and YFV vaccination of infants <9 months of age has been contraindicated since the 1960's due to high rates of vaccine-associated encephalitis in this age group. More recently, YFV vaccination has been found to cause severe viscerotropic disease in a substantial number of patients >60 years of age (an incidence rate of approximately 1:50,000 doses administered) and these cases result in approximately 50% mortality. This indicates that YFV vaccination is not only contraindicated in infants, but is also not recommended in the elderly due to the increased risk of severe and life-threatening disease. Increased monitoring efforts have also documented several cases of vaccine-related fatalities in young, otherwise healthy adults with no known pre- existing immune deficiencies. The overall (all ages) mortality rate following YFV vaccination is estimated at 1 to 2 deaths per million doses – but there is currently no alternative to live YFV vaccination. In this proposal, we will prepare an inactivated YFV vaccine under GMP conditions and perform the necessary safety, potency, and stability studies required for a future IND submission to the FDA. This vaccine is based on proprietary new technology used to develop inactivated vaccine formulations that can be administered to vulnerable populations such as infants and the elderly, in addition to other healthy populations. Preliminary data is provided that demonstrates an H2O2-based inactivated YFV vaccine is feasible to manufacture, highly immunogenic, and provides full protective immunity against lethal viscerotropic yellow fever. In this project, we will prepare clinical grade vaccine under cGMP conditions, perform in vitro and in vivo safety/toxicity tests, and determine vaccine potency and long-term stability. The successful completion of these objectives will result in cGMP-grade vaccine material suitable for future initiation of a Phase I clinical trial.

Public Health Relevance Statement

PROJECT NARRATIVE: In this Phase IIB proposal, we show the significant progress that was made during the Phase II award period and provide exciting new preliminary data demonstrating the antigenicity, immunogenicity, and protective efficacy of a proprietary new vaccine platform that can be used to develop a safer and highly effective vaccine against yellow fever.

NIH Spending Category

Biodefense | Biotechnology | Emerging Infectious Diseases | Immunization | Infectious Diseases | Orphan Drug | Pediatric | Prevention | Rare Diseases | Vaccine Related | Vector-Borne Diseases

Project Terms

Adult | Age | Age-Months | Age-Years | Attenuated | Attenuated Vaccines | Award | Cell Line | Centers for Disease Control and Prevention (U.S.) | Cessation of life | Chemistry | Clinical | Country | Cyclic GMP | Data | Detection | Developing Countries | Development | Disease | Dose | Elderly | Emerging Communicable Diseases | Encephalitis | Engineering | Fatality rate | Foundations | Future | Generations | Goals | Growth | Head | Hemorrhage | Hospitalization | Hydrogen Peroxide | Immune | Immunity | In Vitro | Inactivated Vaccines | Incidence | Industry | Infant | Infrastructure | Investigation | Knowledge | Lead | Life | Macaca mulatta | Modeling | Modernization | Monitor | Morbidity - disease rate | Oral Poliovirus Vaccine | Paralysed | Patients

Read More

Details

Contact PI/ Project Leader

Name
AMANNA, IAN JAMES

Other PIs

Name
SLIFKA, MARK K

Program Official

Name

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Contact PI/Project Leader
AMANNA, IAN JAMES Other PIs

Awardee Organization
NAJIT TECHNOLOGIES, INC.

Organization

Name
NAJIT TECHNOLOGIES, INC.

City
Beaverton

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Domestic For-Profits

State Code
OR

Congressional District
01

Other Information

FOA
PA-16-302

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

Fiscal Year
2019

Award Notice Date
16-January-2019

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
147965243

CFDA Code
855

Project Start Date
01-July-2008

Project End Date
31-January-2021

Budget Start Date
01-February-2019

Budget End Date
31-January-2020

Project Funding Information for 2019

Total Funding
$996,895

Direct Costs
$0

Indirect Costs
$0

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$996,895

NIH Categorical Spending

Click here for more information on NIH Categorical Spending

Funding IC	FY Total Cost by IC	NIH Spending Category
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$996,895	Biodefense; Biotechnology; Emerging Infectious Diseases; Immunization; Infectious Diseases; Orphan Drug; Pediatric; Prevention; Rare Diseases; Vaccine Related; Vector-Borne Diseases;

Sub Projects

No Sub Projects information available for 5R44AI079898-07

Publications

No Publications available for 5R44AI079898-07

Patents

No Patents information available for 5R44AI079898-07

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.

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No Clinical Studies information available for 5R44AI079898-07

News and More

Related News Releases

No news release information available for 5R44AI079898-07

History

No Historical information available for 5R44AI079898-07

Similar Projects

No Similar Projects information available for 5R44AI079898-07

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