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Novel synthetic TLR4 agonists

Project Number
2R44AI136081-02

Contact PI/Project Leader
KHALAF, JUHIENAH

Awardee Organization
INIMMUNE CORPORATION

Description

Abstract Text

Project Summary There are currently no approved vaccines for most emerging biological pathogens (Ebola, Chikungunya, MERS CoV, SARS, Zika), opportunistic infections (S. aureus, Candidiasis, adenovirus) or potential bioterrorism agents (Y. pestis, B. Pseudomallei, F. tularensis, Bunyaviridae, Flaviviridae), and therapeutic interventions such as antibiotics and antivirals are only effective for a select few pathogens. A promising approach for rapidly neutralizing the risk of pathogen exposure is the use of immunomodulators capable of eliciting a robust innate immune response within hours of administration that would provide protective resistance against a wide range of infectious diseases. Proof-of-principle has been established that a new class of chemically and metabolically more stable synthetic TLR4 agonists provide safe and effective protection to mice when administered intranasally two days before a lethal influenza virus challenge. In this Phase II application, we will further optimize these new synthetic TLR4 agonists and formulations for stability, potency and safety, and optimize an administration schedule to provide weeks-long non-specific resistance against influenza virus. We will also assess the potential toxicity of the new TLR4 agonists in mice and develop a scalable cGMP synthesis of the lead candidate. This phase II proposal has the potential to develop a new broad-spectrum immunomodulator that would provide non-specific protective resistance (NSR) against a wide range of biological pathogens, and is primarily targeted for preventing upper respiratory tract infections in individuals or populations at risk for emerging or opportunistic pathogen exposure. Such treatment could reduce morbidity and mortality associated with seasonal or **pandemic** influenza viruses as well as other respiratory pathogens of significant medical concern. The work proposed herein will comprise the pre-clinical basis for IND-filing and human clinical trials using a safe and effective synthetic TLR4 agonist for individuals or populations with a high risk of exposure to seasonal and **pandemic** influenza viruses.

Public Health Relevance Statement

Project Narrative There are currently no approved vaccines for most emerging biological pathogens (Ebola, Chikungunya, MERS CoV, SARS, Zika), opportunistic infections (S. aureus, Candidiasis, adenovirus) or bioterrorism agents (Y. pestis, B. Pseudomallei, F. tularensis, Bunyaviridae, Flaviviridae), and therapeutic interventions such as antibiotics and antivirals are only effective for a select few pathogens. A promising approach for rapidly neutralizing the risk of pathogen exposure is the use of immunomodulators capable of eliciting a rapid robust innate immune response that would provide protective resistance against a wide range of biological pathogens. This proposal seeks to develop a new class of chemically and metabolically more stable synthetic Toll-like receptor 4 (TLR4) agonists for the development of a safe self-administered intranasal broad-spectrum immune-therapeutic with effective anti-viral and anti-bacterial activity to prevent upper respiratory tract infections in individuals or populations at risk for emerging or opportunistic pathogen exposure.

NIH Spending Category

Biodefense | Biotechnology | Clinical Research | Emerging Infectious Diseases | Immunotherapy | Infectious Diseases | Influenza | Orphan Drug | Pneumonia & Influenza | Rare Diseases | Vector-Borne Diseases

Project Terms

Adenoviruses | Agonist | Anti-Bacterial Agents | Antibiotics | Antiviral Agents | Benchmarking | Biological | Biological Products | Bioterrorism | Bunyaviridae | Burkholderia pseudomallei | Candidiasis | Cells | Chemicals | Clinical Trials | Communicable Diseases | Cyclic GMP | Development | Dose | Ebola virus | Embryo | Esters | Evaluation | Exposure to | Flaviviridae | Formulation | Francisella tularensis | Glycosides | Hour | Human | Immune | Immunomodulators | Immunotherapeutic agent | In Vitro | Individual | Influenza | Innate Immune Response | Investigation | Lead | Liposomes | Mediating | Medical | Metabolic | Middle East Respiratory Syndrome Coronavirus | Modeling | Modification | Molecular | Morbidity - disease rate | Mus | Opportunistic Infections

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Contact PI/Project Leader
KHALAF, JUHIENAH

Awardee Organization
INIMMUNE CORPORATION

juhienah.k.khalaf@inimmune.com

Organization

Name
INIMMUNE CORPORATION

City
MISSOULA

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Domestic For-Profits

State Code
MT

Congressional District
At-Large

Other Information

FOA
PA-18-574

Study Section
Special Emphasis Panel[ZRG1 BCMB-G (10)]

Fiscal Year
2019

Award Notice Date
30-August-2019

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
080350279

CFDA Code
855

Project Start Date
09-February-2018

Project End Date
31-August-2021

Budget Start Date
01-September-2019

Budget End Date
31-August-2020

Project Funding Information for 2019

Total Funding
$437,073

Direct Costs
$0

Indirect Costs
$0

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$437,073

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	$437,073	Biodefense; Biotechnology; Clinical Research; Emerging Infectious Diseases; Immunotherapy; Infectious Diseases; Influenza; Orphan Drug; Pneumonia & Influenza; Rare Diseases; Vector-Borne Diseases;

Sub Projects

No Sub Projects information available for 2R44AI136081-02

Publications

No Publications available for 2R44AI136081-02

Patents

No Patents information available for 2R44AI136081-02

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

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Clinical Studies

No Clinical Studies information available for 2R44AI136081-02

News and More

Related News Releases

No news release information available for 2R44AI136081-02

History

No Historical information available for 2R44AI136081-02

Similar Projects

No Similar Projects information available for 2R44AI136081-02