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MR191_ An Immunoprotectant for Marburg Virus

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
5SB1AI082744-08	2SB1AI082744-06	AIMES, RONALD T	MAPP BIOPHARMACEUTICAL, INC.

Description

Abstract Text

PROJECT SUMMARY Mapp Biopharmaceutical, Inc. (Mapp) is developing antibody-based therapeutics to treat a number of infectious agents, including some of the most dangerous known to man: the filoviruses. Marburg virus is a filovirus endemic to Africa and causes an often lethal hemorrhagic fever. Presently there are no approved vaccines or therapeutics to treat Marburg virus infections and this remains a major unmet medical need. Along with its collaborators, Mapp has screened over 100 antibodies from a number of different species that bind to or neutralize Marburg virus in vitro. Several of these have been shown to block the infection of cells and a few have shown potency when tested in animal models of Marburg. Recently, several fully-human monoclonal antibodies have been identified and recovered from a Marburg virus infection survivor. MR191, the lead candidate and the focus of this proposal, has been shown to completely protect non-human primates when challenged with a lethal dose of Marburg virus or the related Ravn virus. Mapp proposes to develop MR191 as a therapeutic candidate to treat Marburg and Ravn virus infections. A Chinese Hamster Ovary (CHO) cell line to produce MR191 will be created, characterized, and cell banks will be generated. This cell line will support production of MR191 at a research scale that will be tested in a non-human primate model of Marburg virus infection to determine the therapeutic window (i.e., how late after infection can MR191 be administered and still result in 100% efficacy) as well as dose determination studies (i.e., what is the lowest dose that gives 100% efficacy). Additionally, the toxicity of MR191 will be evaluated in non-human primates and the data will enable the submission of a New Investigational Drug Application (IND) to the U.S. Food and Drug Administration. Upon completion of the scope of this project, Mapp will be positioned to produce MR191 in compliance with current Good Manufacturing Practices (cGMPs) in advance of submitting the IND. This will enable the conduct of the first-in-human studies for this important filovirus MCM.

Public Health Relevance Statement

PROJECT NARRATIVE There are currently no approved medical countermeasures for Marburg virus infections. The efforts outlined in this proposal will aid in the development of a therapeutic drug candidate for treating and potentially preventing infection with Marburg virus. Successful development of MR191 will transform the medical options in the event of a natural outbreak or the intentional use of Marburg virus as a weapon.

NIH Spending Category

Biodefense Biotechnology Emerging Infectious Diseases Immunization Infectious Diseases Orphan Drug Prevention Rare Diseases

Project Terms

Acute Address Aerosols Africa Animal Model Animals Anthrax disease Antibodies Antibody Therapy Binding **Biological** Products **Biological** Response Modifier Therapy Bioreactors Bioterrorism Categories Cell Line Cells Centers for Disease Control and Prevention (U.S.) Chemicals Chinese Hamster Ovary Cell Clinical Research Collaborations Dangerousness Data Development Disease Disease Outbreaks Dose Ebola virus Emerging Communicable Diseases Event Family Filovirus Frankfurt-Marburg Syndrome Virus Grant Health Personnel Iatrogenesis In Vitro Industry Standard Infection Infection prevention Infectious Agent Inhalation Investigational New Drug Application Laboratories Lethal Dose 50 Medical Modeling

Read More

Details

Contact PI/ Project Leader

Name
AIMES, RONALD T

Title
VICE PRESIDENT - NONCLINICAL DEVELOPMENT

Other PIs

Not Applicable

Program Official

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MR191_ An Immunoprotectant for Marburg Virus

Project Number
5SB1AI082744-08

Former Number
2SB1AI082744-06

Contact PI/Project Leader
AIMES, RONALD T

Awardee Organization
MAPP BIOPHARMACEUTICAL, INC.

City
SAN DIEGO

Country
UNITED STATES (US)

Organization Type
Domestic For-Profits

Congressional District
52

Other Information

FOA
PAR-16-027

Study Section
Special Emphasis Panel[ZRG1-ETTN-C(56)R]

Fiscal Year
2019

Award Notice Date
12-June-2019

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
137551797

CFDA Code
855

Project Start Date **01-April-2009**

Project End Date **30-June-2021**

Budget Start Date **01-July-2019**

Budget End Date **30-June-2021**

Project Funding Information for 2019

Total Funding
$1,000,000

Direct Costs
$695,462

Indirect Costs
$239,117

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$1,000,000

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	$1,000,000	Biodefense; Biotechnology; Emerging Infectious Diseases; Immunization; Infectious Diseases; Orphan Drug; Prevention; Rare Diseases;

Sub Projects

No Sub Projects information available for 5SB1AI082744-08

Publications

No Publications available for 5SB1AI082744-08

Patents

No Patents information available for 5SB1AI082744-08

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 5SB1AI082744-08

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Related News Releases

No news release information available for 5SB1AI082744-08

History

No Historical information available for 5SB1AI082744-08

Similar Projects

No Similar Projects information available for 5SB1AI082744-08

Thank you for your feedback!