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Preclinical development of an immunomodulatory agent capable of mitigating SARS-CoV-2 virus related hypercytokinemia

Project Number	Contact PI/Project Leader	Awardee Organization
1R44AI157719-01	CRAIGO, JODI K	CYTOAGENTS, INC.

Description

Abstract Text

Abstract CytoAgents is developing GP1681 (beraprost-314d) to regulate the uncontrolled inflammatory response that can result from viral infections. This inflammatory response is associated with increased disease severity, acute lung injury (ALI), acute respiratory distress syndrome (ARDS), and death. The emergence of novel viruses with **pandemic potential** poses a major threat to world health and security. In particular, the emergence of novel coronaviruses (CoVs) of animal origin in recent decades indicates that these viruses will continue to cross species boundaries and cause outbreaks in humans. The current outbreak of SARS-CoV-2, a highly pathogenic CoV that causes lower respiratory tract infections and severe pneumonia, represents a severe public health emergency and has been declared a global pandemic by the World Health Organization. SARS-CoV-2 has so far infected nearly 3M individuals in 185 countries, resulting in over 200K deaths, with the greatest number of confirmed cases in the U.S. While most individuals with COVID-19 report only mild illness, about 14% develop severe disease requiring hospitalization and oxygen support, and 5% require intensive care. This has resulted in a significant burden on healthcare systems in several countries, as well as a massive economic burden globally. Studies have revealed that the severity of viral disease and negative health outcomes are often associated with an overstimulated cytokine response, rather than the viral load per se. Overactivation of the inflammatory response results in the uncontrolled release of proinflammatory cytokines, known as hypercytokinemia, which contributes to the destruction of lung tissue, and in severe cases, leads to ARDS, multiorgan dysfunction, and death. GP1681 moderates hypercytokinemia and may reduce the duration and severity of many viral diseases, including COVID-19. Evaluation in mouse models has shown notable efficacy of GP1681 in the treatment of influenza. Knowledge of the mechanism of action of GP1681 suggests that it may be equally effective in treating COVID-19. CytoAgents has submitted an Investigational New Drug (IND) Application to the FDA for an influenza indication and received approval to proceed with a Phase 1 study. Additional NIH (NIAID)-funded preclinical studies are also underway in influenza models. To assess the potential of GP1681 for use against COVID-19, the aims of this project are 1) IND-enabling toxicology studies expanding the initial toxicology screens, as longer treatment may be needed given the typical COVID-19 disease course; 2) Pharmacokinetic (PK) analysis in a non-human primate (NHP) model; and 3) Assessment of the efficacy of delayed GP1681 treatment in an NHP model of COVID-19, as therapy in the clinic is typically initiated at some time after viral infection. The outcomes of this project will prepare CytoAgents for an IND application for the use of GP1681 in the treatment of COVID-19.

Public Health Relevance Statement

Narrative The current outbreak of SARS-CoV-2, a highly pathogenic CoV that causes lower respiratory tract infections and severe pneumonia, represents a severe public health emergency. As the severity of viral disease and negative health outcomes are often associated with an overstimulated inflammatory response, rather than the viral load per se, CytoAgents is developing GP1681 (beraprost-314d), an orally available immunomodulatory agent capable of controlling this uncontrolled inflammatory response, as a novel treatment modality for existing and emerging viral diseases, including COVID-19. This change to the prevailing therapeutic paradigm has the potential to radically alter existing clinical practice, leading to faster recovery times, reduced number and length of hospital stays, reduced intensity of respiratory care, lower mortality, and an overall reduction in the healthcare burden, to the significant benefit of patients and society.

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Contact PI/Project Leader
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Awardee Organization
CYTOAGENTS, INC.

Development Disease Disease Outbreaks Dose Drug Kinetics Economic Burden Epitopes Evaluation Functional disorder Funding Health Healthcare Healthcare Systems Hospitalization Human Immune response Immunomodulators Individual Infection

Read More

Details

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Not Applicable

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Organization

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PITTSBURGH

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Domestic For-Profits

State Code
PA

Congressional District
18

Other Information

FOA
PA-19-272

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

Fiscal Year
2021

Award Notice Date
05-March-2021

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
117039872

CFDA Code
855

Project Start Date
06-March-2021

Project End Date
28-February-2023

Budget Start Date
06-March-2021

Budget End Date
28-February-2022

Project Funding Information for 2021

Total Funding
$1,000,000

Direct Costs
$0

Indirect Costs
$0

Year	Funding IC	
2021	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$1,000,000

Sub Projects

Thank you for your feedback!

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No Publications available for 1R44AI157719-01

Patents

No Patents information available for 1R44AI157719-01

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 1R44AI157719-01

Clinical Studies

No Clinical Studies information available for 1R44AI157719-01

News and More

Related News Releases

No news release information available for 1R44AI157719-01

History

No Historical information available for 1R44AI157719-01

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