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Development of superior polymerases for next-generation mRNA therapeutic & vaccine manufacturing

Project Number
2R44GM131548-02

Contact PI/Project Leader
ZIELER, HELGE

Awardee Organization
PRIMORDIAL GENETICS, INC

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Description

Abstract Text

Project Summary/Abstract Messenger ribonucleic acid (**mRNA**) plays key roles in cells and organisms as a carrier of protein-coding information and as a regulator of gene expression. The pharmaceutical industry has begun to exploit the many natural functions of **mRNA** to develop novel therapeutics and vaccines, which promise high efficacy and great flexibility in the prevention and treatment of diseases ranging from cancers and infectious diseases such as hepatitis and HIV to genetic diseases such as cystic fibrosis and rare diseases caused by heritable genetic defects. The expanded effort in **mRNA** therapeutics and **mRNA** vaccines has created a new demand for **mRNA** molecules manufactured in large quantities to precise specifications. In particular, the need to create **mRNA** molecules >1kb in length that are free of unwanted side products, and to incorporate modified nucleotides for more efficient delivery, higher stability and better clinical efficacy, has compounded this manufacturing problem. Although RNAs can be produced enzymatically in vitro with the use of specialized RNA polymerases, the enzymes widely used to produce RNA for R&D purposes are not suited for the demanding specifications that apply to RNA molecules intended for **mRNA** therapeutics and vaccines. A new class of enzymes, highly optimized for synthesis of long RNAs with specific sequences and structures, need to be created to meet this new demand. In a Phase I feasibility project, Primordial Genetics discovered and tested 53 novel RNA polymerases of which 13 were found to be superior to the current enzymes used for RNA manufacturing. On the strength of our Phase I results, the company began to forge connections to RNA therapeutics companies who are very interested in testing our new enzymes. In the proposed Phase II project, we will improve four of these enzymes, characterize the activity of six improved enzymes in detail, and prepare methods and datasets for using these enzymes for clinical **mRNA** manufacturing. Our goal is to create enzymes that can meet the varied needs for manufacturing a diversity of **mRNA** sequences, sizes and chemical structures represented in **mRNA** vaccines and **mRNA** therapeutic products under development. The enzymes discovered and improved in this work will be directly useful for **mRNA** manufacturing applications, and will be licensed or sold to companies developing **mRNA** vaccines and therapeutics as well as companies building RNA manufacturing capabilities.

Public Health Relevance Statement

Project Narrative The principal aim of this project is to develop improved RNA polymerases, enzymes used for manufacturing messenger ribonucleic acid (mRNA), one of the carriers of genetic information in all organisms. Medicines and vaccines based on mRNA have steadily gained attention and investment as potentially revolutionary ways of treating and protecting against a wide spectrum of diseases, but are currently limited by the difficulty associated with production of clinical quantities of intact, high-quality mRNA that is efficiently taken up and used by the human body. Development of novel mRNA polymerases will help accelerate the development and production of this novel and highly promising class of therapeutics and vaccines and will impact the prevention and treatment of cancers, viral diseases such as HIV and Hepatitis B, and genetic diseases such as cystic fibrosis.

NIH Spending Category

Biotechnology Genetics Immunization Prevention Vaccine Related

Project Terms

Agricultural Crops Agriculture Animals Attention Biotechnology Carrier Proteins Cells Chemical Structure Clinical Code Communicable Diseases Cystic Fibrosis DNA-Directed RNA Polymerase Data Set Development Disease Double-Stranded RNA Drug Industry Enzymes Gene Expression Genetic Genetic Carriers Genetic Diseases Goals HIV Health Hepatitis Hepatitis B Heritability Human Human body In Vitro Industry Investments Length Malignant Neoplasms Medicine Methods Mutation Nucleotides Organism Performance Pharmacologic Substance Phase Play Polymerase Prevention Production Promoter Regions Property RNA RNA chemical synthesis Rare Diseases

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Project Number
2R44GM131548-02

Contact PI/Project Leader
ZIELER, HELGE

helge@primordialgenetics.com

Awardee Organization
PRIMORDIAL GENETICS, INC

Organization

Name
PRIMORDIAL GENETICS, INC

City
SAN DIEGO

Country
UNITED STATES (US)

Department Type
Unavailable

Organization Type
Domestic For-Profits

State Code
CA

Congressional District
49

Other Information

FOA
PA-19-272

Study Section
Special Emphasis Panel[ZRG1 IMST-H (15)]

Fiscal Year
2020

Award Notice Date
05-August-2020

Administering Institutes or Centers
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

DUNS Number
078301879

CFDA Code
859

Project Start Date
17-September-2018

Project End Date
31-January-2022

Budget Start Date
10-August-2020

Budget End Date
31-July-2021

Project Funding Information for 2020

Total Funding
$1,152,047

Direct Costs
$0

Indirect Costs
$0

Year	Funding IC	FY Total Cost by IC
2020	NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES	$1,152,047

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 GENERAL MEDICAL SCIENCES	$1,152,047	Biotechnology; Genetics; Immunization; Prevention; Vaccine Related;

Sub Projects

No Sub Projects information available for 2R44GM131548-02

Publications

No Publications available for 2R44GM131548-02

Patents

No Patents information available for 2R44GM131548-02

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.

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PRIMORDIAL GENETICS, INC

No Clinical Studies information available for 2R44GM131548-02

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Related News Releases

No news release information available for 2R44GM131548-02

History

No Historical information available for 2R44GM131548-02

Similar Projects

No Similar Projects information available for 2R44GM131548-02