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Sirnaomics Ltd.

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2257)

VOLUNTARY ANNOUNCEMENT

**RNAIMMUNE RECEIVES INVESTIGATIONAL NEW DRUG
APPLICATION CLEARANCE FROM U.S. FDA FOR mRNA-BASED
RESPIRATORY SYNCYTIAL VIRUS VACCINE RV-1770**

The board (the “**Board**”) of directors (the “**Directors**”) of Sirnaomics Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**” or “**Sirnaomics**”) hereby informs the shareholders and potential investors of the Company of the attached press release that RNAimmune, Inc. (“**RNAimmune**”), a subsidiary of the Company specializing in mRNA-based vaccines and therapeutics, announces today that RNAimmune has received a safe to proceed notice from the U.S. Food and Drug Administration (FDA), for RNAimmune’s Investigational New Drug (IND) application for an mRNA vaccine (RV-1770) against human Respiratory Syncytial Virus (RSV).

This announcement is made by the Company on a voluntary basis. The Group cannot guarantee that RV-1770 will ultimately be successfully marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Sirnaomics Ltd.
Yang (Patrick) Lu
Chairman and Executive Director

Hong Kong, December 18, 2023

As at the date of this announcement, the Board comprises Dr. Yang Lu (alias Patrick Lu), Dr. Xiaochang Dai and Dr. David Mark Evans as executive Directors, Mr. Mincong Huang and Mr. Jiankang Zhang as non-executive Directors, and Dr. Cheung Hoi Yu, Mr. Fengmao Hua, Ms. Monin Ung and Ms. Shing Mo Han, Yvonne (alias Mrs. Yvonne Law) as independent non-executive Directors.

RNAimmune Receives Investigational New Drug Application Clearance from U.S. FDA for mRNA-Based Respiratory Syncytial Virus Vaccine RV-1770

Germantown, MD, USA | Guangzhou, China, December 18, 2023 — RNAimmune, Inc. (“RNAimmune”), a leading biotech company specializing in mRNA-based vaccines and therapeutics, announced today that it has obtained a green light from the U.S. Food and Drug Administration (FDA) to proceed with its Investigational New Drug application for Phase I clinical trials of RV-1770, an mRNA vaccine targeting the human Respiratory Syncytial Virus (RSV).

RNAimmune will begin a Phase I clinical study to assess the safety and tolerance of RV-1770, a combination of an mRNA-based vaccine with a proprietary lipid nanoparticle formulation, aimed at preventing RSV infection in adults. Healthy volunteers between the ages of 18–49 and an older adult group aged 60–79 will receive a single dose of RV-1770 intramuscularly, using one of three dosage levels: 50 µg, 100 µg, or 200 µg. The study plans to recruit a total of 162 participants divided into two cohorts of younger and older adults with 81 each. All participants will undergo a 12-month post-vaccination monitoring for evaluation of RV-1770’s safety and immunogenicity.

RV-1770 is an innovative mRNA-based vaccine formulation with a unique AI-enhanced design using the sequence of the recent RSV clinical isolate. It demonstrated immunogenic responses and neutralization against both type A and B strains of RSV in preclinical cotton rat studies. “The IND clearance from the FDA represents a significant leap forward in our mission to provide a safe and effective solution against RSV infection and its profound impact on human health,” stated Dr. Dong Shen, President and Chief Executive Officer of RNAimmune. “As we embark on clinical trials aimed at assessing the safety and efficacy of RV-1770, this achievement underscores the potential of RNAimmune’s mRNA technology platform in the battle against RSV and the prevention of associated respiratory diseases.

Dr. Patrick Lu, Chairman of the board of directors of RNAimmune, commented: “RV-1770 has a unique mRNA sequence design with a proprietary nanoparticle formulation that has already shown superb preclinical safety and efficacy. These results clearly demonstrate the strength of RNAimmune’s scientific team in quickly executing on its second vaccine program to move into clinical stage, working effectively with the company’s regulatory team and the FDA.”

Dr. Dewan Zeng, Chief Executive Officer of Zhejiang Innoforce Pharmaceuticals Co., Ltd., the CDMO partner of the RV-1770 project, added: “We sincerely congratulate our partner, RNAimmune, on the FDA clearance of this IND application, and we are honored to be a partner in this innovative journey. We aim to leverage our cutting-edge technologies in ATMP manufacturing to help our partners to bring more effective ATMP to patients worldwide.”

About Respiratory Syncytial Virus

RSV is a major cause of hospitalizations due to pneumonia and bronchiolitis. Substantial morbidity and socioeconomic burden are associated with RSV infection worldwide. Populations with higher susceptibility to developing severe RSV include premature infants, children with chronic lung disease of prematurity or congenital heart disease, elderly individuals aged >65 years, and immunocompromised individuals. In the pediatric population, RSV can lead to long-term sequelae such as wheezing and asthma, which are associated with increased health care costs and reduced quality of life. Treatment for RSV is mainly supportive, and general preventive measures such as good hygiene and isolation are highly recommended. Despite being a significant public health concern, the U.S. has only two approved RSV vaccines, and there is no approved RSV vaccine in China. RNAimmune's RSV mRNA vaccine aims to address this unmet medical need by leveraging messenger RNA technology.

About RNAimmune, Inc.

RNAimmune is a pioneering biotech company dedicated to developing mRNA-based therapeutics and vaccines. With its global headquarters in Germantown, Maryland, USA, and a China headquarters in International BioIsland, Guangzhou, RNAimmune aims to address unmet medical needs by harnessing messenger RNA technology to create innovative solutions for infectious diseases, cancer, and other health challenges. RNAimmune holds a global exclusive right to the proprietary Polypeptide Lipid Nanoparticle (PLNP) technology for mRNA delivery from Sirnaomics. Additionally, RNAimmune possesses various independent proprietary R&D platforms, including artificial intelligence and directed neoantigen prediction, ALEPVA algorithm for nucleic acid sequence design, next-gen lipid nanoparticle (LNP) carrier systems, circular RNA, and self-amplify mRNA platforms. RNAimmune's diverse pipeline includes vaccines for infectious diseases (RSV, COVID-19, influenza, HSV, etc.) and cancer vaccines (RAS, NY-ESO-1), along with mRNA-encoded antibodies. RNAimmune has achieved significant potential and is a leader in the field of mRNA vaccines and therapeutics. For more information about RNAimmune and its RSV mRNA vaccine development, please visit www.rnaimmune.com.

CONTACT:

Dong Shen, MD, PhD

President & Chief Executive Officer, RNAimmune, Inc.

Tel: +1 410 258 5555

Email: dong.shen@rnaimmune.com

U.S. Media Contact:

Alexis Feinberg

Tel: +1 203 939 2225

Email: Alexis.Feinberg@westwicke.com

Asia Media Contact:

Phoenix Fung

Tel: +852 2114 4913

Email: sprg_sirnaomics@sprg.com.hk