

FOR IMMEDIATE RELEASE

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Nagasaki University

neopharma Japan Co., Ltd.

Neopharma Japan Begins Specific Clinical Trials Using 5-Aminolevulinic Acid (5-ALA) on Novel Coronavirus (COVID-19) Patients at Nagasaki University

Nagasaki University ^{*1} (led by President Shigeru Kohno, located in Nagasaki University, Bunkyo-machi 1-14, Nagasaki City, Nagasaki Prefecture, hereinafter referred to as "Nagasaki Uni."), in association with neopharma Japan Co., Ltd. (led by Representative Director Satofumi Kawata, located in Fujimi 2-10-2, Chiyoda Ward, Tokyo City, hereinafter referred to as "NPJ") today announced that they have begun specific clinical trials using 5-aminolevulinic acid ^{*3} (hereinafter referred to as '5-ALA') researched, developed and manufactured by the company, on patients infected with the novel coronavirus (hereinafter referred to as 'COVID-19').

5-ALA is a naturally occurring amino acid that is produced within the cells of humans, animals and plants and animals. It is also contained in foods and is one of the amino acids that we ingest as part of our daily lives. Furthermore, due to its tremendous safety and functionality, it has already been utilized in various healthcare products for more than ten years.

NPJ, in association with Prof. Kiyoshi Kita, Dean of the School of Tropical Medicine and Global Health, Nagasaki University, has focused on this functionality of 5-ALA and has been developing therapeutic agents for malaria. Currently we are conducting clinical research in Laos in association with Director Shigeyuki Kano of the National Center for Global Health and Medicine. As 5-ALA is expected to be effective against a wide range of infectious diseases, we are extensively studying the inhibitory effects of 5-ALA against tropical infectious diseases in association with Nagasaki University, which has a long history of research into tropical diseases.

Against this backdrop, Nagasaki Uni. has begun research on COVID-19 in response to the high societal demand. From the results of an in-vitro cell infection test conducted with the usage of the causative virus, SARS-CoV-2, we discovered that 5-ALA possessed a strong infection-suppressing effect against the infection. The results of this research have been submitted as a paper. ^{*4}

Professor Koichi Izumikawa, Vice President of Nagasaki Uni. (COVID-19 Response) and others have drafted a specific clinical trial for the administration of 5-ALA to patients infected with COVID-19, and as 28/10/2020, this specific clinical trial was officially approved by the Accredited Ethics Committee of Nagasaki Uni. The detailed contents of this specific clinical trial will be published in the clinical study database at a later date. This is a multi-institutional joint study conducted at multiple hospitals, with Nagasaki Uni. Hospital functioning as the core.

COVID-19 presents an ongoing global public health threat, with the development of related therapeutic agents becoming a critical global issue in urgent need of addressing. However, presently the effective treatments for COVID-19 are scarce in number. Meanwhile, there are restrictions on the target patient symptoms relating to the development of therapeutic products, and careful medical observation of issues including side-effects is required.

However, in regards to vaccine development, while development is being promoted by domestic and foreign companies and research institutes, due to the necessities of confirming vaccine efficacy, safety and quality standards, as well as whether or not mass production is possible, it is expected that vaccine development will take a year to be completed.

For these reasons, in the current circumstances of an invisibly spreading infection, many are eagerly awaiting a medical agent that is highly safe, usable for a wide range of patients, and able to be supplied without capacity concerns.

For this specific clinical trial, NPJ shall support the research conducted by Nagasaki Uni. while utilizing our 5-ALA-related knowledge and technology. We hope that 5-ALA will become one of the new preventative and therapeutic treatments against COVID-19.

*¹Nagasaki University

Nagasaki University is a national university established in 1949. The campus was relocated and integrated in the 1950s and 1960s, and the medical faculties and research institutes (such as the School of Medicine, the School of Dentistry, the Nagasaki University Hospital and the Institute of Tropical Disease etc.) are now located in the Sakamoto Campus. Nagasaki University has an outstanding track record in the fields of tropical medicine, infectious diseases and radiological science due to its geographical and historical background, and with its abundant accumulation of research and an unrivaled team of infectious disease researchers, it has become a well-known educational and research base for those studying virulent diseases in Japan and abroad.

<http://www.nagasaki-u.ac.jp/>

*²neopharma Japan Co., Ltd.

neopharma Japan Co., Ltd. was established as a joint venture between Neopharma LLC, which is based in the United Arab Emirates (UAE), and neoALA Co., Ltd. (formerly known as Cosmo ALA Co., Ltd.). The Neopharma Group, based in the UAE, is a multinational pharmaceutical group of companies that manufactures and markets its products with a central focus on Middle Eastern and other newly industrialized countries. neopharma Japan plays an important role in the field of pharmaceutical manufacturing with regards to Neopharma LLC's overseas strategy. Furthermore, neopharma Japan is creating added value for the entire Group through the promotion of research and development of various applications using 5-aminolevulinic acid (5-ALA).

<https://www.neopharmajp.co.jp/>

*³5-aminolevulinic acid (5-ALA)

Human, animals, and plants all maintain their vital functions through the production of energy in the organelles inside their cells called mitochondria. 5-aminolevulinic acid (5-ALA) plays a very important role in ensuring the functionality of these mitochondria. 5-ALA eventually transforms into a substance called "heme" inside the mitochondria. This heme is an essential protein component for producing the energy called "cytochrome". These substances are indispensable for energy production. In short, 5-ALA can be described as an amino-acid that plays a key role in mitochondrial function.

In addition, it is an extremely safe amino acid that has already been utilized in animal feeds, cosmetics, fertilizers, health foods and pet supplements for over ten years. 5-ALA has also been approved for use in the oncology field as a brain and bladder cancer visualizing drug. Furthermore, 5-ALA is known to improve mitochondrial function, with a Phase 3 medical investigator-led clinical trial currently being conducted at Saitama Medical University.

<http://5ala-journal.com/>

*4Paper

The paper is currently undergoing peer-review, and its content may be modified in future, but for now the pre-print manuscript will be viewed on the bioRxiv website.

<https://www.biorxiv.org/>

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