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Nagasaki University (Japan)

neopharma Japan Co., Ltd.

## Notice of Patent Acquisition:

# Patent Granted for 5-Aminolevulinic Acid (5-ALA) Against Novel Coronavirus Infection (COVID-19)

National University Corporation, Nagasaki University\*<sup>1</sup> (represented by Shigeru Kohno , M.D., Ph.D.: hereinafter referred to as 'Nagasaki University'), in association with neopharma Japan Co., Ltd.\*<sup>2</sup> (represented by Satofumi Kawata: hereinafter referred to as 'NPJ'), today announced that they have been granted a patent for the treatment and prevention of the novel coronavirus disease (hereinafter referred to as 'COVID-19') through the usage of 5-aminolevulinic acid\*<sup>3</sup> (hereinafter referred to as '5-ALA'),

### [Patent Outline]

- Publication Number: Patent Publication No. 2022-8060 (P2022-8060A)
- Title of Invention: Therapeutic and/or prophylactic agent for new coronavirus infection (COVID-19)
- Publication Date: 13<sup>th</sup> January 2022 (13/01/2022)

### [Outline]

Ever since the first reports of novel coronavirus (hereinafter referred to as 'SARS-CoV-2') cases in December 2019, more than 150,000 deaths have been reported due to the worldwide surge of COVID-19 patients. Within Japan, COVID-19 infection trends have been closely studied since the beginning of 2020, and at numerous research institutes the causative virus of this pandemic has been placed under intense scrutiny. Until recently, Professor Kiyoshi Kita of Nagasaki University's Dean of the Graduate School of Tropical Medicine and Global Health, in association with NPJ, was focusing on the functional properties of 5-ALA and was making progress in developing anti-malarial drugs. However, in the process of doing so, they realized the effects of 5-ALA could have against SARS-CoV-2 and so began an additional study into COVID-19 as well.

The results of this study demonstrated that 5-ALA can strongly inhibit the infection of SARS-CoV-2 (the virus responsible for COVID-19) in cultured cells. This antiviral effect was observed in both human and non-human cells without significant cytotoxicity\*<sup>4</sup>. In addition, similar studies on previously identified mutant strains also revealed an effectiveness against the Delta strain\*<sup>5</sup>. More recently, a concentration-dependent inhibition of Omicron strain infections was also observed in cell-based studies\*<sup>6</sup>.

Based on the results from these joint research projects, Nagasaki University and NPJ filed a patent application, which was then granted to us. We expected that 5-ALA will become one of the main substances used to fight against COVID-19 in the future.

## [Glossary]

### \*<sup>1</sup> Nagasaki 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) are now found on 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/>

### \*<sup>2</sup> neopharma Japan Co., Ltd.

neopharma Japan was established as a joint venture between Neopharma LLC, based in the United Arab Emirates (UAE) and neoALA Co., Ltd (formally known as COSMO ALA Co., Ltd). The Neopharma Group is an international pharmaceutical company headquartered in the United Arab Emirates (UAE), which is developing its pharmaceutical manufacturing and sales business mainly in the Middle East and other developing nations. neopharma Japan plays a key role in Neopharma LLC's overseas strategy within the area of pharmaceutical manufacturing. Furthermore, neopharma Japan is creating new added value for the Group

as a whole by promoting research and development of various applications of 5-amino-levulinic acid (5-ALA)

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

**\*3 5-Aminolevulinic Acid (5-ALA)**

Human, animals, and plants all maintain their vital functions by producing energy within the organelles called mitochondria inside their cells. 5-aminolevulinic acid (5-ALA) plays an especially significant role in ensuring the functionality of these mitochondria. Inside the mitochondria, 5-ALA is transformed first into “heme” and then into a substance called “cytochrome”, substances which are indispensable for energy production. It is also a very safe amino acid that has been used in health foods, cosmetics, pet supplements, animal feed and fertilizers for over a decade. In the field of oncology, 5-ALA is also approved as a diagnostic agent for the visualization of brain tumors and bladder cancer. In addition, 5-ALA is known to improve mitochondrial function, and a phase 3 physician-led clinical trial for mitochondrial disease is underway, led by Saitama Medical University.

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

**\*4 Released on February 9<sup>th</sup>, 2021**

“5-Aminolevulinic Acid (5-ALA) Found to have Infection Inhibition Effect Against Novel Coronavirus (COVID-19) Causative Virus”

<https://www.neopharmajp.co.jp/library/592faa4a16088b6a0b777d96/6022465c38c81ba70586c2e2.pdf>

**\*5 Released on January 11<sup>st</sup>, 2021**

“Confirmation of Infection Inhibition Effectiveness of 5-Aminolevulinic Acid (5-ALA) Against Novel Coronavirus (COVID-19) Causative Virus and Various Mutant Strains”

<https://www.neopharmajp.co.jp/library/592faa4a16088b6a0b777d96/61dcd5c5c4215add1045b2cb.pdf>

**\*6 Presented at 10th Annual Meeting of the Porphyrin-ALA Symposium on May 5<sup>th</sup>, 2022**

“Confirmation of Inhibitory Effects of 5-Aminolevulinic Acid (5-ALA) Against Novel Coronavirus (COVID-19) Omicron Strain Infections” PAPER SUBMITTED FOR PUBLICATION



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