

## Kowa Press Release

# Confirmed antiviral effect of Kowa ivermectin on "Omicron strain"

Kowa Co., Ltd. (hereinafter referred to as "Kowa") is the investigational drug "Ivermectin" used in Phase III clinical trials (development code: K-237) for the treatment of new coronavirus (SARS-CoV-2) infections. From a joint research (non-clinical trial) with Kitasato University, it was confirmed that the Omicron strain has the same antiviral effect as the existing mutant strain (alpha beta gamma delta strain).

As announced in July 2021, Kowa directly from Professor Satoshi Omura, a special honorary professor at Kitasato University, who won the Nobel Prize in Physiology or Medicine, about conducting clinical trials of ivermectin as a therapeutic drug for new coronavirus infections. He believes that it is the mission of the pharmaceutical company to contribute to the treatment of coronavirus infections and protect the health of the people, and clinical trials to confirm the efficacy and safety of ivermectin against new coronavirus infections.

Ivermectin has been distributed by WHO to infected areas for over 30 years as a treatment for parasitic infections. Especially in some African countries, it has been confirmed to be safe enough for volunteers to distribute directly to people.

In addition, ivermectin has been reported to have the effects of suppressing the invasion of SARS-CoV-2 into cells and inhibiting replication, and is expected to be applied as a therapeutic drug (tablet) for new coronavirus infections as drug repositioning. I am. In this clinical trial, the dosage and administration are different from those already approved for the treatment of parasitic infections, but the efficacy and safety are being confirmed in the clinical trial.

Kowa will contribute to the treatment of new coronavirus infections by confirming the clinical effect of ivermectin on SARS-CoV-2 and providing it to the public as soon as possible.

\* Overseas, it was reported that patients use high-content ivermectin for animals, which is dangerous for humans, and harmful events occur. Kowa is the standard for conducting clinical trials of pharmaceuticals for humans. Ivermectin clinical trials are conducted in accordance with the strict standards set by GCP (Good Clinical Practice).



## PRESS RELEASE

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### Kowa Ivermectin Confirmation of antiviral effect against Omicron strain

("Kowa") announced today that it has confirmed that the investigational drug ivermectin, which is being used in a Phase III clinical trial (development code: K-237) for the treatment of new coronavirus (SARS-CoV-2) infections, has the same antiviral effect against existing mutant strains ( In addition to the existing mutant strains (alpha, beta, gamma, and delta), we have **confirmed that ivermectin has the same antiviral effect against the Omicron strain.**

As announced in 2021March7 2012, Kowa received a request directly from Professor Satoshi Omura of Kitasato University, winner of the Nobel Prize in Physiology or Medicine, to conduct clinical trials of ivermectin as a treatment for new coronavirus infections. We believe that it is our mission as a pharmaceutical company to contribute to the treatment of new coronavirus infections and protect the health of the people, and we are conducting clinical trials to confirm the efficacy and safety of ivermectin for new coronavirus infections.

Ivermectin has been **distributed by WHO to infected areas** as a treatment for parasitic infections for **over a year30**. In some countries, especially in Africa, it has been **so safe that volunteers distribute it directly to people.** In addition, ivermectin has been reported to inhibit the intracellular entry and replication of SARS-CoV-2, and is expected to be applied as a drug repositioning agent (tablet) for the treatment of new coronavirus infections. This clinical trial differs from the dosage and administration already approved for the treatment of parasitic infections, but we are currently confirming the efficacy and safety in the clinical trial.

By confirming the clinical efficacy of ivermectin against SARS-CoV-2 and providing it to the public as soon as possible, Kowa will make a small contribution to the treatment of new coronavirus infections.

Although there have been reports overseas that patients have used ivermectin for veterinary use with a high content that is dangerous for humans, and that adverse events have occurred, Kowa is conducting clinical trials of ivermectin in accordance with the strict standards set forth in the Good Clinical Practice (GCP) which is the standard for conducting