PRESSRELEASE





New Clinical Data on the Efficacy of Antiviral Treatments for Post-COVID-19 Condition

- In a large-scale post-marketing clinical study conducted by Tokushukai Medical Group, the incidence of post-COVID-19 conditions (PCC) (commonly referred to as Long COVID) was approximately 26% among patients who did not receive oral antiviral treatment.
- Oral antiviral treatment reduced the risk of developing PCC by a statistically significant 14% compared to no antivirals.
- These findings suggest that oral antiviral treatment may help prevent the onset of PCC.

OSAKA, Japan, November 5, 2025 - General Incorporated Association Tokushukai (Location: Chiyoda-ku, Tokyo; Chairperson of the Board: Shinichi Higashiue, M.D.; hereinafter "Tokushukai Medical Group") and Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced new clinical data from the ANCHOR study, a large-scale post-marketing clinical study conducted by Tokushukai Medical Group in patients diagnosed with COVID-19. The primary endpoint results were presented at the 8th ISRV-AVG Meeting and 3rd IMRP held in Singapore (September 17–20, 2025), and secondary endpoint results were presented at APCCMI 2025 in Thailand (November 2–4, 2025).

The World Health Organization (WHO) defines PCC as occurring in individuals with a history of probable or confirmed SARS-CoV-2 infection, typically around three months after the onset of COVID-19, with symptoms lasting for at least two months and not explainable by an alternative diagnosis¹. Common symptoms include fatigue, shortness of breath, loss of taste or smell, cognitive dysfunction but also others which generally have an impact on everyday functioning². PCC is a significant challenge not only in Japan but globally. However, evidence supporting the effectiveness of antiviral in preventing these symptoms has been limited. In response, the Tokushukai Medical Group conducted a large-scale clinical study (ANCHOR study) targeting outpatients diagnosed with COVID-19. This study evaluated the impact of antiviral use on the PCC.

This multi-center, nationwide, prospective observational study enrolled outpatients aged ≥12 years diagnosed with COVID-19 at 51 Tokushukai Group hospitals across Japan. As a collaborative research partner, Shionogi contributed to the execution of this study.

The clinical study presented this time included approximately 9,000 cases enrolled between February 1 and October 31, 2024. The primary endpoint of this study, "the incidence of PCC," in the antiviral and non-antiviral group, defined as persistence of any of five pre-specified symptoms (fatigue, dyspnea or respiratory distress, cough, smell disorder, taste disorder) on both Days 28 and 84, excluding symptoms not attributed to COVID-19. The incidence of post-COVID-19 symptoms was then evaluated based on this definition. The incidence of PCC was approximately 26% in the non-antiviral group (N=5,518) and approximately 24% in the antiviral group (N=2,181, combined group of ensitrelvir, nirmatrelvir/ritonavir, and molnupiravir). Antiviral treatment significantly reduced the risk by about 14% (adjusted risk ratio: 0.86 [95% CI: 0.78–0.93]; P < 0.001). For ensitrelvir alone, the risk was also significantly reduced by about 14% compared to non-antiviral treatment (adjusted risk ratio: 0.86 [95% CI: 0.79–0.95]; P = 0.002).

For the secondary endpoint, "Frequency of COVID-19–related re-consultations within 28 days," no significant risk reduction was observed in the overall antiviral group compared to the non-antiviral group (adjusted risk ratio: 0.93 [95% CI: 0.83-1.04]; P = 0.266). However, ensitrelyir alone showed a significant 12% reduction in revisit risk (adjusted risk ratio: 0.88 [95% CI: 0.78-0.99]; P = 0.030).

These findings suggest that oral antiviral treatment may contribute to improving acute-phase symptoms, reducing the incidence of PCC, and potentially lowering re-visit frequency.

"Managing PCC remains a major unmet medical need. We are pleased that the ANCHOR study results indicate that antiviral treatment during the acute phase may help prevent the onset of PCC. This study represents an important step toward new directions in COVID-19 treatment and is expected to inform clinical decision-making and long-term health management," said Dr. Makoto Hibino, MD, principal investigator of this study, Deputy Director of Shonan Oiso Hospital, and Chair of the Tokushukai Respiratory Committee.

In the "Guidelines for the Clinical Management of COVID-19 issued by five academic societies" published on October 17, 2025, it is stated that "the fundamental principle of clinical care for infectious diseases, particularly viral infections, is early diagnosis and early treatment. This approach may help prevent severe illness, alleviate symptoms, and enable early return to social activities for individuals, while also reducing the burden on society by preventing widespread transmission and decreasing the number of hospitalized patients." Based on these principles outlined in the guidelines, Tokushukai Group and Shionogi will continue to collaborate in accumulating evidence related to COVID-19 and delivering it back to clinical practice.

About ANCHOR Study

The purpose of ANCHOR study is to collect information of the clinical course of patients with COVID-19 treated at Tokushukai hospitals with and without antiviral drugs and to explore the clinical course in the acute phase, the frequency of severe disease, and frequency of PCC by the treatment, after adjusting by patient background including risk factor(s) and symptoms at the time of registration. In this study, Shionogi is participating as a collaborative research partner.

About Tokushukai Medical Group

Tokushukai Medical Group philosophy is "All livin beings are created equal". Under this philosophy, we continuously strive for realizing "Anybody in the society is to receive the best possible medical care in anywhere, at whenever necessary". From Emergency Medical Care, an origin of medical care, to preventive health care, chronic medical care and advanced medical care, we provide the optimal medical care. For more information on Tokushukai Medical Group, please visit https://www.tokushukai.or.jp/en/

About Shionogi & Co., Ltd.

For over 60 years, Shionogi has been engaged in the research and development of infectious disease treatments. Identifying "Protect people from the threat of infectious diseases" as a material issue (materiality) to be addressed, the company is working towards the realization of comprehensive infectious disease care. As a leading company in the field of infectious diseases, Shionogi is strengthening its initiatives, including collaborations with external partners, to provide healthcare solutions to a broader audience and continuously address a wide range of infectious diseases. For more information on Shionogi & Co., Ltd., please visit https://www.shionogi.com/global/en

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form: https://www.shionogi.com/global/en/contact.html

Reference List:

- 1. WHO, Post COVID-19 conditions; https://www.who.int/teams/health-care-readiness/post-covid-19-condition
- 2. Ministry of Health, Labour and Welfare (Japan), *Guidelines for COVID-19 Clinical Management Supplement: Management of Post-COVID-19 Conditions, Version 3.1, 2025*; https://www.mhlw.go.jp/content/10900000/001422904.pdf
- 3. Guidelines for the Clinical Management of COVID-19 issued by five academic societies 2025