Press Release

Shionogi Filed the Application for Marketing Approval of Th2 Chemokine TARC Kit "HISCL® TARC reagent" to Assist in Predicting the Exacerbation of COVID-19

OSAKA, Japan, April, 26, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D. ; hereafter "Shionogi") is pleased to announce that on April 16th, Shionogi filed application for marketing approval of Th2 chemokine TARC kit "HISCL® TARC reagent", which is being marketed as anin vitro diagnostics, for the purpose of assisting in predicting exacerbation in novel coronavirus (SARS-CoV-2)-positive patients.

This test kit is available as an aid in assessing the severity of atopic dermatitis. It is possible to easily measure TARC, which is a type of chemokine (strain name: CCL17) that increases as the symptomatic worsening of atopic dermatitis. Through the latest clinical research, the National Center for Global Health and Medicine has identified TARC, which is a useful biomarker for predicting the aggravation of COVID-19 patients from an early stage with a single measurement[1]. It has been confirmed that the serum level of TARC remain low value in patients with severe symptoms of COVID-19 from early onset to aggravation. Furthermore, no specific disease showing low TARC level was found when examined in various chronic diseases, suggesting that it is possible to predict the prognosis of COVID-19 even in patients with underlying diseases.

COVID-19 is a disease that is at risk of rapidly becoming more severe later even if early symptoms are mild. Due to difficulties determining the progression of symptoms, continuous observations and treatments are required at medical institutions and accommodation facilities. It is therefore, the society recognizes the necessity to relief medical system overwhelmed by increasing the number of people receiving medical treatment at these facilities and reduce the risk of future medical collapse. The test kit is expected to identify patients with a high risk of aggravation from the early stage of COVID-19 onset, and to lead to individual optimal measures such as hospitalization, accommodation treatment, and home treatment. It means helping to solve medical problems.

Shionogi is committed to "Protecting people worldwide from the threat of infectious diseases" as our key focus. In addition to our continued efforts for the research and development of therapeutics, we are also pursuing total care for infectious diseases, through awareness building, prevention, diagnosis, and treatment of exacerbations, as well as addressing the infection itself. We will continue to strive to fulfill our social responsibility and seek to contribute to re-establishing the safety and security of society by bringing forward new tools and technologies for the prevention, diagnosis, and treatment of COVID-19 to support early containment of the pandemic.

About TARC

TARC (thymus and activation-regulated chemokine) is a protein composed of 71 amino acids and is one of the chemokine group that migrates Th2 cells, which are one of the lymphocytes, to the inflamed site. It is suggested that an abnormal immune balance between Th1 cells and Th2 cells[2,3] may be involved in the aggravation of COVID-19.

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 outcomes 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, unavailability 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.

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References

1. Sugiyama M, Kinoshita N, Ide S, Nomoto H. Serum CCL17 level becomes a predictive marker to distinguish between mild/moderate and severe/critical disease in patients with COVID-19. Gene 766(2021)145145
2. Int Immunol. 1999, 11:81-88.
3. FASEB J. 1991, 5:171-177.

Our efforts against COVID-19 are updated on our website as needed. A considerable amount of valuable information on COVID-19 from other websites is also summarized on this page, so please use it for reference: SHIONOGI website