Fujifilm announces the Start of a New Phase III Clinical Trial of Anti-influenza Drug Avigan® Tablet in Japan, Targeting COVID-19 Patients

TOKYO, April 21, 2021—FUJIFILM Toyama Chemical Co., Ltd. (FUJIFILM Toyama Chemical; President: Junji Okada) has announced the initiation of a new phase III clinical trial in Japan concerning its anti-influenza drug Avigan® Tablet (Avigan; generic name: favipiravir), targeting patients infected with novel coronavirus infections (COVID-19). The trial is a double-blind, placebo-controlled clinical trial*1 to investigate the drug's efficacy and safety in patients with early-onset COVID-19 with risk factors for progression to severe symptoms.

While the pathology of COVID-19 has yet to be fully elucidated, there has been a necessity for effective treatment drugs as quickly as possible. FUJIFILM Toyama Chemical therefore initiated a phase III clinical trial for Avigan in Japan in March 2020, targeting COVID-19 patients with non-severe pneumonia. Since the primary endpoint*2 had been met*3 with the statistically significant difference in the clinical trial, the company filed an Application for Partial Changes to manufacturing and marketing approval matters of Avigan.*4

With COVID-19, numerous cases have been reported showing that many elderly patients saw their disease become severe and, that even with mild cases, if they had risk factors for the disease to become severe, such as underlying disease or obesity, their condition rapidly deteriorated. FUJIFILM Toyama Chemical had been investigating a new clinical trial for establishing a treatment method that prevents the disease from becoming severe.

The new phase III clinical trial in Japan is targeting patients with early-onset COVID-19 having risk factors for progression to severe symptoms. The trial design was based on the findings from the phase III clinical trial implemented last year, that Avigan expedited the improvement of symptoms in early-onset patients. The primary endpoint would be the ratio of patients whose condition has become severe by comparing Avigan and placebo groups. The subjects of this trial are COVID-19 patients aged 50 and older, and those who are at risk of developing serious conditions, such as those with underlying diseases and obesity. The enrollment should be made within 72 hours of onset.

The Fujifilm Group will work to deliver the treatment drug to COVID-19 patients as soon as possible, and contribute to ending the spread of COVID-19.

*1 A method of clinical tests performed without letting either the physicians (observers) or the patients know which drug is being administered. (The actual drug or a placebo)
*2 Time to negative conversion of detectable SARS-CoV2 viral RNA in the RT-PCR assays, and to alleviation of symptoms (body temperature, oxygen saturation and chest images).
*3 The primary endpoint has been confirmed with the statistically significant difference (P value = 0.0136). The median value of primary endpoint was 11.9 days for the Avigan group and 14.7 days for the placebo group. The adjusted hazard ratio showed 1.593 (95% confidence interval of 1.024 – 2.479).
*4 The application is under review.

<About Avigan® Tablets>

Avigan® is an anti-influenza drug that had obtained domestic manufacturing and marketing approval in March 2014 with the treatment of new or reemerging influenza viruses as the indication. Administration of the drug to patients is considered if a new or re-emerging influenza virus infection has occurred to which other anti-influenza virus drugs prove ineffective or produce only insufficient effects, and the government decides to use the drug as a measure to cope with this influenza virus.

Since it has the mechanism of action for selectively inhibiting RNA polymerase involved in influenza viral replication, it is also expected to be effective against the novel coronavirus, which is an RNA virus of the same type as influenza viruses.

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