Preliminary results of an early intervention clinical study of amantadine in patients with SARS-COV-2 infection

Prof. Konrad Rejdak – Head of the research project "Use of Amantadine to Prevent Progression and Treat COVID-19 Symptoms in Patients Infected with the SARS-COV-2 Virus", presented the preliminary results of the study.

The aim of the project is to investigate the efficacy of COVID-19 in the early stages in preventing progression to acute respiratory failure and neurological consequences in a double-blind, placebo-controlled study.

Background

Participants in the "Use of amantadine to prevent progression and treat COVID-19 symptoms in patients infected with SARS-CoV-2" study are patients infected with SARS-CoV-2 and who have risk factors for severe COVID-19 (age and comorbidities). No later than day 5 after laboratory confirmation of SARS-COV-2 virus infection, amantadine or placebo is added to standard medical care.

Results of the Halftime Analysis

Of approximately 500 patients infected with SARS-CoV-2 and receiving early medical care at 7 clinical sites (active recruitment), 110 patients were enrolled and randomized into the study. Preliminary analysis to assess safety and therapeutic efficacy was performed on 93 clinical trial participants in both groups (Placebo vs Amantadine) who completed the 15-day follow-up period (double-blind phase). On the day of study inclusion (Day 1), 19.6% of patients who were randomized to receive amantadine and 14.6% of patients who were randomized to receive placebo required hospitalization, while the remaining participants remained in outpatient observation. A mild course of disease was observed in most patients in both groups. During the follow-up to date, there were no significant differences in the Amantadine vs. Placebo group of patients. At the same time, no significant complications or death was observed in the group of patients taking Amantadine. In the safety analysis, there were 41 reports of adverse effects (17 in the Amantadine group and 24 in the Placebo group).

The Medical Research Agency has decided to continue the clinical trial based on the preliminary results, with planned recruitment through April 15, 2022 in the double-blinded portion and extended follow-up in the open-label portion for an additional 6 months.