INTERIM REPORT ON THE RESULTS OF A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Conclusion

Study title: open randomized multicenter comparative study of the efficacy and safety of the drug Areplivir, film-coated tablets (PROMOMED RUS LLC, Russia) in patients hospitalized with COVID-19.

Study drug: Replevin, tablets, film-coated (OOO "PROMOMED RUS", Russia).

Studied indication: COVID-19.

Study design: open randomized multicenter comparative.

Research sponsor: PROMOMED RUS LLC, Russia.

Research Protocol : no. FAV032020.

Date and version of the Protocol: version 2.0 dated 10.06.2020.

Phase of clinical development: phase III.

Dates of the study: II quarter of 2020 – IV quarter of 2020.

Responsible person on the part of the Sponsor: General Director of the management organization PROMOMED DM LLC, Marina Penkova.

Date of report preparation: 19.06.2020.

This study, including archiving of the main research documents, is performed in accordance with the ICH E6 recommendations "Good clinical practice" and the Rules of good clinical practice approved by the Eurasian economic Commission.

Conclusion

This interim report is based on data received from 80 patients (40 patients in the Areplivir group + 40 patients in the standard therapy group).

The safety assessment was based on a statistical analysis of safety endpoints. The frequency of patients belonging to the studied drug Replevin with reported cases of AES amounted to 22.50% (9/40). The frequency of patients in the standard therapy group with registered cases of NYA was 17.50% (7/40). As a result of a comparative analysis of NSAS by their presence, severity, cause-effect relationship with therapy, and outcome, no intergroup differences were found.

The evaluation of the effectiveness of the studied drugs was based on a statistical analysis of primary and secondary endpoints. According to the study Protocol, it was necessary to estimate the Time (in days) to improve the clinical status on a categorical ordinal scale of clinical improvement. The median time (in days) to improve clinical status was 8 days in the Areplivir group and 10 days in the standard therapy group. The comparative analysis revealed significant differences in the time to improvement of the patient's clinical status (p=0.041).

In accordance with the study Protocol, it was necessary to evaluate the frequency of improvement of clinical status on a categorical ordinal scale of clinical improvement of 2 or more categories at Visit 3. In the Areplivir group, the proportion of patients with improved clinical status by 2 or more categories was 30%, in the standard therapy group-5%. As a result of a comparative analysis of the frequency of cases of

improvement of clinical status by 2 or more categories, significant differences between the study groups were revealed (p=0.00326).

Since there were statistically significant differences in the time (in days) before improvement of the patient's clinical status, as well as in the proportion of patients who achieved improvement of the clinical status on the categorical ordinal scale of clinical improvement of 2 or more categories by Visit 3, the hypothesis of superiority of the drug Areplivir over standard therapy can be considered proven.

As a result of a comparative analysis of the frequency of patients with COVID-19 elimination according to PCR analysis for Visit 3, significant differences were found between the Areplivir group and the standard therapy group (Fisher's Exact criterion, p=0.045).

Thus, according to the results of interim data analysis, the clinical study "open randomized multicenter comparative study of the effectiveness and safety of the drug Areplivir, film-coated tablets (PROMOMED RUS LLC, Russia) in patients hospitalized with COVID-19" demonstrated the superiority of therapy with the drug Areplivir, film-coated tablets (PROMOMED RUS LLC, Russia) over standard therapy in patients hospitalized with COVID-19.