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Clinical trial using MAF for hospitalized COVID-19 patients in Ukraine

In June 2020 we applied to the COVID-19 Scientific Technical Triage of the US FDA for the evaluation of the rationale to study the efficacy of **MAF Capsules** in COVID-19 treatment. The US FDA in PreIND 151946 meeting response recommended a small proof of concept (POC) study as the initial step prior to the large-scale trial be run. The US FDA indicated recommendations including the major study endpoints addressing the investigation of **MAF Capsules** efficacy as a potential new drug was implemented in the proposed study design.

The recommended efficacy endpoints were also implemented in the open-label randomized clinical trial that started in Ukraine in November 2020 to assess the efficacy and safety of dietary supplements **MAF Capsules**, 148 mg and **M Capsules**, 148 mg in addition to standard of care (SOC) compared with SOC in the treatment of hospitalized non-critical COVID-19 patients.

Summary of preliminary results of clinical study

The ongoing interim study results showed a decrease in all-cause mortality and necessity of oxygen supply, as the mortality was 4/15 in the control group, vs 0/16 and 1/17 of currently enrolled patients in the **MAF Capsules** and **M Capsules** groups respectively. The mean duration of supplemental oxygen was 8.5 days in the control group, vs 4.1 and 5.1 days in the **MAF Capsules** and **M Capsules** groups respectively.

MAF Capsules, which is under investigational new drug process, is a dietary supplement that targets guts mucosal immunity to modulate macrophages functionality, limiting epithelial damage, and controlling inflammation response during COVID-19.

Clinical trial groups:

- Control group
- **MAF Capsules** (colostrum MAF) group
- **M Capsules** (whey MAF) group

Patients randomized 1:1:1 to:

1. SOC (standard of care)
2. SOC plus **MAF Capsules** (148 mg, 3 caps. TID for 14 days)
3. SOC plus **M Capsules** (148 mg, 3 caps. TID for 14 days)

As compared to the control, both MAF groups showed a clear trend in decreasing mortality

- No adverse events
- Decrease in the mortality rate
- Decrease in necessity and duration of supplemental oxygen
- Decrease in time to recovery
- Decrease in time until hospital discharge
- Preventing of respiratory failure
- Restoring the base-line decreased lymphocytes count