EOM Pharmaceutical Holdings Announces Topline Results of its COVID-19 Clinical Trial of EOM613 in Brazil

Results indicate that EOM613 treatment mitigates cytokine release in patients with COVID-19 pulmonary vascular inflammation

MONTVALE, NJ -- September 6, 2023 -- **EOM Pharmaceutical Holdings, Inc** (OTC: IMUC) ("EOM") today announced the results of its completed clinical trial in hospitalized COVID-19 patients with severe symptoms treated with its investigational immune-regulating drug product EOM613. The trial was conducted in Brazil.

This exploratory Phase 1/2a clinical trial (NCT05212532), designated RESCUE, was a proof-of-concept, open-label study evaluating the safety, tolerability, and preliminary efficacy measures, such as the effects on serum cytokines, when EOM613 was added to the standard-of-care therapy. The trial included two cohorts of patients hospitalized for COVID-19: one cohort was in the intensive care unit (ICU) and the other cohort was not (non-ICU). The study was conducted at four different medical centers in the Brazilian states of Sao Paolo and Goaia.

The trial was originally designed to enroll a total of 40 patients – 20 in each cohort. The trial was redesigned, however, due to challenges in patient enrollment during the COVID-19 pandemic as a result of Brazil's successful vaccination program which led to a reduction in eligible hospitalized patients. The redesigned trial enrolled a total of 23 patients eligible for evaluation. The study's Principal Investigator was Florentino Cardoso Filho, MD, at the Casa de Saude Hospital in Campinas, Sao Paolo, and former President of the Brazilian Medical Association.

Topline Results

The study's topline results indicate that:

- EOM613, administered by subcutaneous (SC) injection was well-tolerated by hospitalized COVID-19 patients.

- EOM613 treatment produced a reduction in certain pro-inflammatory serum cytokine levels in line with its postulated mechanism of action of immune modulation.

- The non-ICU cohort was comprised of patients hospitalized for COVID-19 receiving supplemental oxygen therapy by mask or nasal prongs, corresponding to degrees 4-5 of the WHO Ordinal Clinical Scale for Disease Severity (WHO-OSDS). The ICU cohort was comprised of patients hospitalized for COVID-19 under mechanical ventilation in an ICU, corresponding to degrees 6 or 7 of WHO-OSDS.

- Both cohorts received the standard-of-care therapy for COVID-19 as defined by the participating hospitals, with the addition of any medications necessary for the study participant's special needs, such as diabetes, hypertension, etc., but excluding other experimental drugs and any drugs used off-label.

- Of the total of 23 patients enrolled in the study, 5 patients were in the non-ICU cohort and 18 patients with severe respiratory inflammation symptoms requiring mechanical ventilation support were in the ICU cohort. For the non-ICU patients, EOM613 was administered SC at a dose of 2 mL once daily (QD) for 10 days, for a total of 20 mL. The ICU cohort received EOM613 SC at a dose of 2 mL twice daily (BID) for 5 days followed by 2 mL once daily (QD) for 5 days, for a total of 30 mL. All patients were followed for 28 days. A clinical data evaluation was made of the evolution of WHO-OSDS, and laboratory exams and adverse events were compared with historic controls treated for COVID-19 at the same hospitals.

- The results of the trial indicate that, EOM613 administered SC at a dose level of 2 mL QD for 10 days was well tolerated in COVID-19 non-ICU patients. Study drug was discontinued for only one enrolled patient in the ICU cohort after the first day of treatment due to hemodynamic worsening (Grade 4). In ICU patients receiving a dose level of 2 mL BID for 5 days followed by 2 mL QD for 5 days, a somewhat higher frequency of adverse events (AEs) of the cardiovascular system was observed than in the non-ICU cohort as would be expected with mechanically ventilated patients, but these AEs were not deemed related to EOM613 treatment by the clinical investigators. Both treatment group regimens had no negative effect on clinical laboratory parameters (complete blood count, SMA-18 metabolic panel, biochemistry) of patients with COVID-19 infection.

- Post-baseline clinically significant beneficial changes were seen with EOM613 treatment for two of the blood serum cytokines involved in the cytokine storm in hospitalized COVID-19 patients, namely, soluble interleukin-2 receptor (sIL-2R) and interleukin-10 (IL-10). In the seriously affected ICU cohort, changes were also observed in other cytokines, such as TNF-α, IL-1β, IL-6 and IL-13, in line with EOM613's mechanism of action as a broad-spectrum immune regulator.

- For example, at screening levels of sIL-2R cytokine were meaningfully higher in the ICU cohort patients with mean values of 1721.69 (± 720.31) pg/mL (median1602.30 pg/mL). sIL-2R levels decreased during the study in both study cohorts. A statistically significant change from baseline was observed on Day 8 in the ICU cohort, i.e., a drop of -512.15 (± 698.10), median -412.80 ($p = 0.0214$). Similarly, in the non-ICU cohort the mean baseline value at screening on Day 28 showed mean IL-2R levels were 588.55 (± 537.76) pg/mL (median 484.60) in the non-ICU cohort and 726.96 (± 331.70) pg/mL (median 861.50) in the ICU cohort. Median changes from baseline in sIL2-R were -485.35 pg/mL and -444.90 pg/mL, respectively.

Shalom Z. Hirschman, MD, Chief Medical Officer of EOM Pharmaceuticals, stated: “I am encouraged by the results of this trial indicating that EOM613 was well-tolerated even in this group of seriously affected hospitalized COVID-19 patients, as it had earlier been shown to be trials in patients with AIDS, cancer cachexia and rheumatoid arthritis. Furthermore, I am pleased that the serum cytokine measurements in COVID-19 patients validate the putative mechanism of action of EOM613 as a broad-spectrum immunomodulating agent affecting pro- and anti-inflammatory cytokine levels, as these results are consistent with previous results in cell culture in immune cells. Both sIL-2R and IL-10 cytokines have been implicated in the scientific literature as biomarkers for the progression of severe COVID-19 infection, with elevated levels of sIL-2R in particular being a predictor of hospital mortality. Thus, an agent that can be shown to diminish serum levels of this cytokine may prove beneficial. Cytokines such as sIL-2R are also associated in various other chronic inflammatory conditions such as rheumatoid arthritis in which enhanced T-cell activation is involved.”

“The results of this trial further elucidate EOM613’s mechanism of action in patients, thus corroborating the earlier preclinical lab research, and suggesting broader potential utility. This provides an additional support for EOM’s future clinical drug development in various chronic inflammatory diseases,” added Irach B. Taraporewala, PhD, CEO of EOM Pharmaceuticals. “A well-tolerated broad-spectrum immune regulating agent such as EOM613 which can modulate multiple cytokines involved in disease pathogenesis could have meaningful therapeutic value. We look forward to conducting additional investigation of EOM613’s potential utility.”

About EOM613

EOM’s lead asset, EOM613, is an investigational, novel peptide-nucleic acid solution immunomodulator believed to have both anti- and pro-inflammatory broad-spectrum cytokine effects. In human cell culture studies, EOM613 demonstrated a unique “dynamic dual action” by suppressing or stimulating monocytes and macrophages depending on the activation state and environment of those key immune cells. It is hypothesized that this dynamic dual-action may overcome a limitation of many approved immunomodulators that only reduce the inflammatory state without achieving immune system balance

About EOM Pharmaceutical Holdings, Inc.

EOM Pharmaceutical Holdings, Inc. is a clinical-stage company focused on developing novel drugs with the potential to transform therapeutic paradigms and improve quality of life in patients suffering from debilitating and sometimes deadly diseases. The Company was founded with a specific vision to pursue innovative approaches to rescue, repair, and restore health of patients with urgent and unmet medical needs. For more information about EOM Pharmaceuticals, please visit www.eompharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify these statements by forward-looking words such as “may,” “will,” “continue,” “anticipate,” “intend,” “could,” “project,” “expect” or the negative or plural of these words or similar expressions, and other similar terms. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, EOM’s ability to develop and commercialize its product candidates; EOM’s ability to obtain and maintain regulatory approval of product candidates; EOM’s ability to operate in a competitive industry and compete successfully against competitors that have greater resources; EOM’s reliance on third parties; EOM’s ability to obtain and adequately protect intellectual property rights for product candidates; and the effects of COVID-19 on clinical programs and EOM’s business operations. Any forward-looking statements in this press release speak only as of the date of this press release. EOM assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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