



**EOM PHARMACEUTICALS ANNOUNCES FIRST PATIENTS DOSED IN *R*<sup>1</sup>: RESCUE PHASE 1/2A OPEN-LABEL TRIAL EVALUATING EOM613 IN HOSPITALIZED COVID-19 PATIENTS WITH SEVERE SYMPTOMS IN BRAZIL**

EOM613 is an investigational, novel peptide-nucleic acid solution immunomodulator, believed to have both anti- and pro-inflammatory broad-spectrum cytokine effects

**MONTVALE, N.J.** – August 24, 2021 -- EOM Pharmaceuticals, Inc., a privately held, clinical-stage company, announced the first patients have been dosed in *R*<sup>1</sup>: RESCUE, a proof-of-concept Phase 1/2a open-label multicenter clinical study in Brazil to evaluate safety, tolerability, and preliminary efficacy of EOM613 in hospitalized COVID-19 infected patients with severe symptoms.

“We are pleased to announce the first patients have been dosed in our Phase 1/2a open-label trial,” said Irach B. Taraporewala, Ph.D., EOM Chief Executive Officer and Director. “This is the first step in clinically evaluating what we believe is EOM613’s unique mechanism of action to address cytokine storms in COVID-19 patients. The study reinforces our commitment to pursue innovative approaches to meet urgent and unmet global medical needs.”

“I have experienced firsthand the severity of the COVID-19 crisis in Brazil and its deadly impact on our community and the hospital system,” said Florentino de Araujo Cardoso Filho, M.D., Principal Investigator and CMO - Chief Medical Officer of Hospital Care, in Campinas, São Paulo, Brazil. “The first dosing of patients in this clinical trial is an important milestone to potentially bring a promising treatment to COVID-19 patients in Brazil. I am excited to be part of this journey to potentially help those suffering from this devastating pandemic.”

**About RESCUE Trial**

*R*<sup>1</sup>: RESCUE is a Phase 1/2a open-label clinical study in Brazil evaluating EOM613 in severe COVID-19 patients with “cytokine storm” immune responses. The study is intended to inform the Brazil regulatory pathway, which could include an Emergency Use Authorization (EUA) and full ANVISA regulatory approval.

The *R*<sup>1</sup>: RESCUE trial will be recruiting hospitalized COVID-19 patients at hospital sites in Brazil. The 28-day study is expected to enroll approximately 40 patients to assess the safety, tolerability, and preliminary efficacy of EOM613 in non-ICU hospitalized patients and ICU hospitalized patients. The primary endpoint is safety and tolerability of EOM613 in hospitalized COVID-19 patients. The secondary endpoints are the effect of EOM613 on selected anti- and pro-inflammatory cytokines, and correlation of changes in cytokine levels with clinical outcomes, such as time to discharge from the hospital or ICU. EOM expects to announce data from this trial in Q4 2021.

**About Severe Effects of COVID-19**

COVID-19 is a dangerous, potentially fatal respiratory condition caused by SARS-CoV-2. For people who have symptoms, illness can range from mild to severe. Adults 65 years and older and people of any age with underlying medical conditions are at higher risk for severe illness.<sup>1</sup>

Aggressive inflammatory responses to SARS-CoV-2 such as cytokine storms, a type of small protein that can cause inflammation in the lungs and other organs, can lead to acute respiratory distress syndrome (ARDS), which is a cause of death in 70% of fatal COVID-9 cases.<sup>2</sup> Certain risk factors increase the likelihood of the development of ARDS in people with COVID-19, including advanced age, diabetes, a history of cardiac disease, and high blood pressure.<sup>3</sup>

### **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.<sup>4,5,6</sup> 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. EOM613 has a de-risked development program supported by promising early-clinical-stage safety and efficacy data across multiple therapeutic applications associated with hyperimmune responses, including cachexia associated with HIV/AIDS or cancer,<sup>7,8</sup> and rheumatoid arthritis.<sup>9</sup>

### **About EOM Pharmaceuticals**

EOM Pharmaceuticals is a privately held, 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](http://www.eompharma.com).

\*EOM613 has had other names, including Product R, OHR118, AVR118, and OHR/AVR118.

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### **Forward-Looking Statements**

This press release may contain forward-looking statements as such term is understood in the federal securities laws, including, among others, statements regarding the potential to develop a COVID-19 therapy. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in drug research and development. Any forward-looking statements in this press release speak only as of the date of this press release, and EOM Pharmaceuticals, Inc. undertakes no obligation to update or revise the statements in the future, even if new information becomes available.

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## References

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<sup>2</sup> Hojyo S, Uchida M, Tanaka K, et al. How COVID-19 induces cytokine storm with high mortality. *Inflamm Regen*. 2020;40:37. Published 2020 Oct 1. doi:10.1186/s41232-020-00146-3

<sup>3</sup> Yale Medicine. Fact Sheets: Acute Respiratory Distress Syndrome (ARDS). Available at: <https://www.yalemedicine.org/conditions/ards>. Accessed December 23, 2020.

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<sup>7</sup> Levett PN, Hirschman SZ, Roach TC, Broome H, Alexander RJ, Fraser HS. Randomized, placebo-controlled trial of product R, a peptide-nucleic acid immunomodulator, in the treatment of adults infected with HIV. *HIV Clin Trials*. 2002 Jul-Aug;3(4):272-8. doi: 10.1310/N34A-653T-ABF5-8Q1R. PMID: 12187500.

<sup>8</sup> Chasen M, Bhargava R, Hirschman SZ, Taraporewala IB. A Phase II study of OHR/AVR118 in anorexia-cachexia. Poster presentation at: the 7th Cachexia conference, Kobe/Osaka, Japan, December 9--11, 2013

<sup>9</sup> Data on file, EOM Pharmaceuticals.