



**For Immediate Release**

**EOM PHARMACEUTICALS ANNOUNCES ITS PRE-IND MEETING REQUEST WITH U.S. FDA TO EVALUATE PLANS FOR A PHASE 2 CLINICAL TRIAL OF ITS INVESTIGATIONAL DUAL-ACTING, BROAD-SPECTRUM IMMUNOMODULATOR IN COVID-19 PATIENTS**

EOM developing IND for evaluating EOM613 safety and efficacy to treat the most severe effects of COVID-19, including ARDS

**MONTVALE, N.J.** – December 23, 2020 -- EOM Pharmaceuticals, Inc., a privately held, clinical-stage company, today announced it has filed a pre-Investigational New Drug Application (pre-IND) meeting request and complete pre-IND briefing documents with the U.S. Food and Drug Administration (FDA) to discuss the company's plans to evaluate the safety and efficacy of its dual-acting, broad-spectrum immunomodulator drug candidate EOM613 in a Phase 2 clinical trial treating complications of hospitalized COVID-19 patients, including Acute Respiratory Distress Syndrome (ARDS).

The pre-IND meeting request is supported by previously completed Phase 2 clinical trials with EOM613\* in cachexic AIDS patients and advanced cancer patients with cachexia, a cytokine- and chemokine-related body wasting syndrome. In those studies, EOM613 treatment was shown to be both safe and capable of mitigating the cytokine- and chemokine-driven symptoms of cachexia, stabilizing or increasing patient weight, and also improving quality-of-life measures such as the Karnofsky Performance Status and Simmonds Functional assessment scores.<sup>1,2,3,4,5</sup>

"We are pleased to have taken this important step in advancing our EOM613 COVID-19 program as we pursue EOM613 as the first dual-acting, broad-spectrum immunomodulator designed to treat infection-related hyperimmune reactions and autoimmune disorders," said Irach B. Taraporewala, Ph.D., EOM Chief Executive Officer and Director. "We look forward to finalizing our Phase 2 clinical study design and protocol for EOM613 with the advice and guidance of the FDA and to initiating our trial at a leading university medical center in the United States, where COVID-19 continues to have a devastating impact on the lives of patients and their families."

**About COVID-19-Associated Acute Respiratory Distress Syndrome**

ARDS is a dangerous, potentially fatal respiratory condition in which the lungs acquire a widespread injury that reduces their ability to provide the body with enough oxygen. The condition causes fluid buildup in the lungs, which in turn decreases blood oxygen to critically low levels. ARDS is a medical emergency,<sup>6</sup> and a major complication in severe cases of COVID-19, affecting 42% of patients presenting with COVID-19 pneumonia and 61–81% of those requiring intensive care.<sup>7</sup>

ARDS also triggers an adverse immune response, causing a release of cytokines, a type of small protein that can cause inflammation in the lungs and other organs. This inflammation, in combination with low levels of blood oxygen, can lead to such life-threatening problems as organ failure and sometimes

multiple organ failure. 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>6</sup>

### **About EOM613**

EOM613 is an investigational, first-in-class, dual-acting, broad-spectrum immunomodulator designed to provide both an anti-inflammatory effect at the site of cytokine and chemokine overactivity, and a pro-inflammatory effect, when needed. EOM613 is designed to counteract the most severe inflammatory effects of viruses, such as cytokine storm or hyperimmune response following infection with the novel coronavirus that causes COVID-19, autoimmune attacks that cause joint damage and pain associated with rheumatoid arthritis, and cytokine- and chemokine-related body-wasting syndromes such as cachexia. By re-establishing balance, EOM613 may rescue, repair, and restore an immune system that has been confronted by an invading antigen, pathogen, or virus. This dual-acting, broad-spectrum approach may overcome a key limitation of conventional immunomodulators. It is administered as a subcutaneous injection, unlike conventional immunomodulators which often require intravenous infusion. EOM613 has already demonstrated clinical improvements in various disease states and immune-related biomarkers and general tolerability across five Phase 2 clinical trials in patients with cachexia associated with AIDS and cancer, and in patients with rheumatoid arthritis. EOM613 is efficiently manufactured from readily available materials.

### **About EOM Pharmaceuticals**

EOM Pharmaceuticals is a privately held, clinical-stage pharmaceutical company with a pipeline of products that have already shown clinical relevance in multiple Phase 2 clinical trials. The Company's mission is to pursue innovative approaches with novel types of small molecule therapeutics to solve the problems of some of today's most urgent and unmet medical needs. EOM's pipeline is built on proprietary innovations designed to rescue, repair, and restore health. These innovations include the development of the first-and-only dual-acting, broad-spectrum immunomodulator EOM613, which has the potential to treat systemic illness due to an intense inflammatory immune reaction, including COVID-19, influenza, and cancer cachexia, and its advanced formulation of EOM147, the first potential topically administered eye drop to treat retinal diseases. Multiple Phase 2 trials suggest EOM613 and EOM147 have improved relevant clinical measures and are well tolerated. 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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<sup>1</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>2</sup> D'Olimpio JT, Hirschman SZ, Shtemer Z, Didiego M. Anti-cachectic effects of a novel peptide nucleic acid: Preliminary results of a phase I/II clinical trial. DOI: 10.1200/jco.2004.22.90140.8087 (presentation abstract). *Journal of Clinical Oncology*. July 15, 2004; 22, no. 14\_suppl 8087-8087.

<sup>3</sup> D'Olimpio JT, Chasen MR, Sharma R, Diego M, Gullo V, MacDonald N. Phase II study of AVR118 in the management of cancer related anorexia/cachexia. DOI: 10.1200/jco.2009.27.15\_suppl.e20631 (presentation abstract). *Journal of Clinical Oncology* 2009; 27, no. 15\_suppl., e20631-e20631.

<sup>4</sup> Chasen M, Hirschman SZ, Bhargava R. Phase II study of the novel peptide-nucleic acid OHR118 in the management of cancer-related anorexia/cachexia. *J Am Med Dir Assoc*. 2011 Jan;12(1):62-7. doi: 10.1016/j.jamda.2010.02.012. Epub 2010 May 15. PMID: 21194662.

<sup>5</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>6</sup> Yale Medicine. Fact Sheets: Acute Respiratory Distress Syndrome (ARDS). Available at: <https://www.yalemedicine.org/conditions/ards>. Accessed December 23, 2020.

<sup>7</sup> Gibson PG, Qin L, Puah SH. COVID-19 acute respiratory distress syndrome (ARDS): clinical features and differences from typical pre-COVID-19 ARDS. *Med J Aust*. 2020;213(2):54-56.e1. doi:10.5694/mja2.50674