



EOM Pharmaceutical Holdings Provides an Update on its Lead Drug Candidate EOM613

MONTVALE, NJ –November 7, 2023 --**EOM Pharmaceutical Holdings, Inc.** (OTC: IMUC) (“EOM”) today provides an update on its clinical program for its lead drug candidate EOM613. EOM613 is a peptide-nucleic acid-based broad spectrum immune regulating agent that acts on both key pro-inflammatory and anti-inflammatory cytokines with potential therapeutic utility in treating a variety of acute and chronic inflammatory conditions.

This agent has been previously shown to regulate cytokine expression in a variety of immune cells in cell culture, and more recently in a Phase 1/2a human clinical trial in patients hospitalized COVID-19 with cytokine-driven respiratory inflammation. Recently reported results of this trial, named RESCUE, indicated marked beneficial reductions of the soluble interleukin-2 receptor protein (sIL-2R) cytokine levels in treated patients, with a concomitant mitigation of the release of the pro-inflammatory cytokine tumor necrosis factor alpha (TNF-alpha).

This clinical finding is of particular interest since the pathophysiology of inflammatory bowel disease (IBD) is known to be largely driven by the release of inflammatory cytokines in the gastrointestinal tract, in particular TNF-alpha, interleukin 12 (IL-12), interleukin-23 (IL-23) and sIL-2R. In light of these clinical trial results, the company is currently preparing to initiate an EOM613 clinical program in Crohn’s disease.

Inflammatory bowel disease is a chronic condition that encompasses Crohn’s disease and ulcerative colitis. Together, the incidence of these forms of IBD, according to the data from the Centers for Disease Control and Prevention (CDC), is 3.1 million adults (1.3% of all adults) in the United States alone with an overall prevalence in 2023 of 825 per 100,000. Despite the availability of therapies such as anti-cytokine antibodies, corticosteroids and aminosalicylate classes of drugs, treatment failures are common, and the use of these drugs has been associated with some severe side-effects such as the risk of opportunistic infections. The estimated global market for IBD therapies is expected to reach \$27.0 billion annually by 2030.

“EOM is now planning and designing a future clinical program for Crohn’s disease patients who have failed currently available therapies or are unable to tolerate them,” stated Shalom Z. Hirschman, MD, Chief Medical Officer of EOM. “In previous clinical trials in AIDS, cancer cachexia and COVID-19 patients, EOM613 was demonstrated to be well-tolerated, even in very sick patients. A broad-spectrum immune regulating agent that regulates pro- and anti-inflammatory cytokines in patients without the risk of severe side effects associated with the use of antibody or corticosteroid drugs could prove to be beneficial in the treatment of Crohn’s disease and ulcerative colitis.”

EOM is planning to undertake IND-enabling animal toxicology and preclinical studies relevant to Crohn's disease. EOM is also assembling a team of key opinion leader gastroenterologists, who are experts in clinical research relating to novel treatment approaches to IBD, to advise on the design and execution of the planned clinical trial.

On September 1, 2023, EOM filed a provisional patent application for EOM613 for use in inflammatory bowel disease with the United States Patent and Trademark Office (USPTO).

According to the USPTO, a provisional application for a patent is a U.S. national application filed under [35 U.S.C. §111\(b\)](#). A provisional application is not required to have a formal patent claim or an oath or declaration. Provisional applications also should not include any information disclosure (prior art) statement since provisional applications are not examined. A provisional application provides the means to establish an early effective filing date in a later filed nonprovisional patent application filed under [35 U.S.C. §111\(a\)](#). It also allows the term "Patent Pending" to be applied in connection with the description of the invention.

“EOM's priority is to initiate a clinical program in inflammatory bowel disease as soon as possible,” added Irach B. Taraporewala, PhD, Chief Executive Officer of EOM. “We believe that EOM613 could potentially make an important contribution to the treatment of this disease and the welfare of patients as a potentially well-tolerated alternative to current biologic and non-biologic therapies.”

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.

In a prior Phase 2 open-label study, EOM613 had previously shown beneficial effects in stabilizing the weight and improving the functional status of patients with advanced malignancies who also had cancer cachexia (the debilitating condition of muscle wasting, fatigue and weight loss) in Stage III and Stage IV cancer, the pathophysiology of which is largely driven by pro-inflammatory cytokines. As resources allow, EOM plans to conduct future clinical trials in cancer cachexia, for which there are no approved drug therapies in the US.

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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