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EOM613 Backgrounder

EOM613: Novel Immunomodulator



About EOM613

EOM613 is an investigational, novel peptide-nucleic acid solution immunomodulator believed to have both anti- and pro-inflammatory effects. It is the lead product candidate being developed by EOM Pharmaceuticals, a privately held, clinical-stage company led by an accomplished team of scientists and pharmaceutical executives with a deep legacy in multiple therapeutic areas.

The Phase 1/2a open-label clinical study in Brazil will evaluate EOM613 in severe COVID-19 patients with “cytokine storm” immune responses. In addition to COVID-19, additional subsequent studies of EOM613 are being planned to assess its potential to improve the quality of life for people with debilitating and potentially fatal diseases such as infectious diseases; autoimmune diseases including rheumatoid arthritis; and cachexia associated with AIDS and cancer.



EOM613 Mechanism of Action

EOM613 is a peptide nucleic-acid solution and is believed to have both anti-inflammatory 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.^{1,2,3} 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,^{4,5} and rheumatoid arthritis.⁶

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Upcoming Clinical Trials

COVID-19 tissue and organ damage that leads to patient fatalities may be associated with hyperinflammatory effects and the release of large amounts of cytokines and chemokines in the body. A Phase 1/2a clinical trial for EOM613 is underway in Brazil to address the most severe effects of COVID-19.

The study is intended to inform the Brazil regulatory pathway, which could include an Emergency Use Authorization (EUA) and full ANVISA regulatory approval.



EOM613 Clinical Trial Overview

EOM613* has already demonstrated clinical improvements in various biomarkers and tolerability across clinical trials in patients with cachexia associated with AIDS and cancer, and in patients with rheumatoid arthritis. The drug is efficiently manufactured from readily available materials.

Disease/Disorder, Source	Study Type and Design	# of Patients	Efficacy Findings	Safety/Tolerability Findings
HIV/AIDS¹ (Levett et al., 2002)	<ul style="list-style-type: none"> Phase 1/2, randomized, double-blind, placebo-controlled trial Conducted in Barbados 	43 (21 EOM613, 22 placebo)	<ul style="list-style-type: none"> CD4 lymphocyte counts increased vs baseline more in EOM613 group vs placebo group (p=0.013) 4 EOM613 patients (but no placebo patients) had significant viral load declines Body weight increased vs baseline in EOM613 group (p=0.003) whereas placebo group had a mean weight loss (p=0.003 for group difference) 	<ul style="list-style-type: none"> EOM613 injections generally well tolerated Some patients reported transient mild pain at injection site No toxic effects of EOM613 reported by patients or observed by physicians
Rheumatoid Arthritis (RA)² (EOM data on file)	<ul style="list-style-type: none"> Phase 2, open-label trial Patients given EOM613 1 mL twice daily for 15 days, then once daily for 75 days Conducted in Argentina 	27 patients who met American College of Rheumatology criteria for mild to moderately severe RA	<p>After the 3 months of EOM613 therapy, all patients:</p> <ul style="list-style-type: none"> Responded with amelioration of symptoms Had a significant decreases in joint pain Had increased mobility of the joints Showed objective signs of decreased inflammation of affected joints Considered efficacy as excellent 	<ul style="list-style-type: none"> No major side effects observed or reported All patients considered tolerability as excellent
Cancer Cachexia³ (Chasen et al., 2013)	<ul style="list-style-type: none"> Phase 2, open-label trial Conducted in Canada 	29 enrolled patients with advanced cancer and cachexia	<ul style="list-style-type: none"> Stabilization of weight, lean body mass and body fat Appetite increased (p=0.001) and total PG-SGA scores improved significantly (p=0.025) Enhanced quality of life and Karnofsky Performance Status 	EOM613 was well tolerated with minimal side effects

* In these and other past reports, EOM613 has had other names, including Product R, OHR118, AVR118, and OHR/AVR118.

References:

1) 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. 2) EOM Data on File. 3) Chasen M, Bhargava R, Hirschman SZ, Taraporewala I. Phase II study of OHR/AVR118 in anorexia-cachexia. Abstract of poster presentation at the 7th Cachexia conference, Kobe/Osaka, Japan, December 9-11, 2013. *J Cachexia Sarcopenia Muscle* 2013;4(4):335-6.

