Powering Relentless Science™

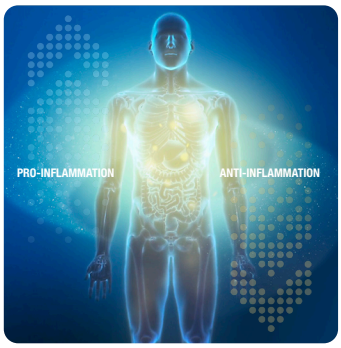
EOM613 Backgrounder

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.

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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/AIDS[1] (Levett et al., 2002)	• Phase 1/2, randomized, double-blind, placebo-controlled trial • Conducted in Barbados	43 (21 EOM613, 22 placebo)	• 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)	• 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)	• Phase 2, open-label trial • Patients given EOM613 l 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	After the 3 months of EOM613 therapy, all patients: • 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	• **No major side effects observed or reported** • **All patients considered tolerability as excellent**
Cancer Cachexia[3] (Chasen et al., 2013)	• Phase 2, open-label trial • Conducted in Canada	29 enrolled patients with advanced cancer and cachexia	• 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.

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