Powering Relentless Science™

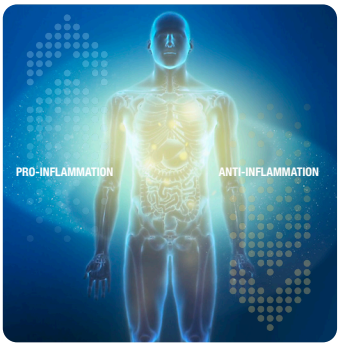
EOM613 Backgrounder

EOM613: Rescue. Repair. Restore.™

About EOM613

EOM613 is an investigational, first-in-class, dual-acting, broad-spectrum immunomodulator designed to drive 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.

A proposed Phase 2 study will examine the potential for EOM613 to rescue the body's immune system from cytokine and chemokine storms and hyperimmune response caused by severe COVID-19 infection, and repair and restore the immune system back to its normal state. 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 designed to have both an anti-inflammatory effect specifically at the site of cytokine and chemokine overactivity, and a pro-inflammatory effect, when needed to restore physiological balance. Distinct from conventional immunomodulators, which generally target a single process of the immune response either pro- or anti-inflammatory, EOM613 is designed to modulate the body's fine balance of pro-inflammatory and anti-inflammatory cytokines and chemokines to counteract the most severe inflammatory effects of viruses, such as cytokine storm following infection with the novel coronavirus that causes COVID-19, autoimmune attacks that cause joint damage and pain associated with rheumatoid arthritis, and chemokine-related body-wasting syndromes such as cachexia.

By re-establishing normal physiological immune 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. 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. It is administered as a subcutaneous injection, unlike conventional immunomodulators which often require intravenous infusion.

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. Phase 2 clinical trials for EOM613 are planned for Q1 2021 to address the most severe effects of COVID-19.

The potential regulatory pathway for approval includes Compassionate Use, Emergency Use Authorization (EUA) and Fast Track Designation by the U.S. Food and Drug Administration (FDA).

MEDIA CONTACT:
Dawn Maniglia
TogoRun
917.862.5444
d.maniglia@togorun.com

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EOM613 Clinical Trial Overview

EOM613* has **already demonstrated clinical improvements in various biomarkers and tolerability across five Phase 2 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-Associated Cachexia[1] (Levett et al., 2002)	• Phase 1/2, randomized, double-blind, placebo-controlled trial • Treatment until day 60, follow-up until day 120 • 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) • Episodes for opportunistic infections lower in the drug-treated group (6 in 3 patients) vs placebo (11 in 8 patients) (p=0.076)	• 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**
AIDS/Cancer Cachexia[2] (D'Olimpio et al., 2004)	• Phase 1/2, open-label dosing trial • Conducted in Israel under Ministry of Health IND	• 12 cachectic patients (10 with AIDS, 2 with pancreatic cancer) given EOM613 0.4 mL/d for 28 days • 5 additional AIDS patients were given EOM613 2.0 mL/d • Patients were followed for 28 days after 28-day treatment was completed	**AIDS:** • At 0.4ml dose, 70% of patients had slight weight gain or stabilization, all had increases in appetite by week 4, 60% reported increased energy and activities of daily living (ADL), mean strength increase was 8%, 70% had increased body fat • At 2ml dose, patients improved appetite by week 2, with mean body fat increase of 25% and strength increase of 32%, all had improved energy and ADL by week 3 **Pancreatic Cancer:** • At 0.4 ml dose, both patients had improved weight, percent fat and strength during 28-day treatment period	**No adverse events were noted in either group of patients**
Cancer Cachexia[3] (D'Olimpio et al., 2009)	• Phase 2, open-label trial • Initial treatment for 28 days followed by evaluation (Phase A) • Patients showing benefit in Phase A allowed to continue therapy (Phase B) • Conducted in United States	16 enrolled patients with advanced cancer and cachexia	• As of this report, 7 patients completed Phase A and chose to continue with EOM613 treatment (phase B) • 7/7 and 6/7 patients improved in anorexia and Patient Generated Subjective Global Assessment, respectively • 5/7 patients experienced weight stabilization or gain	**EOM613 was well tolerated and no serious side effects were reported**
Cancer Cachexia[4,5,6] (Chasen et al., 2010 and 2013)	• Phase 2, open-label trial • Initial treatment for 28 days followed by evaluation (Phase A) • Patients showing benefit in Phase A allowed to continue therapy (Phase B) • Conducted in Canada	29 enrolled patients with advanced cancer and cachexia	• 18 patients completed Phase A and 11 of them continued in Phase B up to 153 days • 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**
Rheumatoid Arthritis (RA)[7] (ADVR press release, 2003)	• 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**

* 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)** D'Olimpio JT, Hirschman SZ, Shtemer Z, Didiego M. Anti-cachectic effects of a novel peptide nucleic acid: Preliminary results of a phase 1/2 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. **3)** D'Olimpio JT, Chasen MR, Sharma R, Diego M, Gullo V, MacDonald N. Phase 2 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. **4)** 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. **5)** Chasen M, Bhargava R, Hirschman SZ, Taraporewala IB. A Phase 2 study of OHR/AVR118 in anorexia-cachexia. Poster presentation at: the 7th Cachexia conference, Kobe/Osaka, Japan, December 9–11, 2013. **6)** Chasen M, Bhargava R, Hirschman SZ, Taraporewala I. Phase 2 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. **7)** Advanced Viral Research Corp (ADVR). ADVR reports AVR118 inhibits inflammatory arthritis in animal model and in rheumatoid arthritis patients in human clinical trial. ADVR press release, PR Newswire, December 3, 2003.

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