

## **FDA Grants Cosmo Pharmaceuticals both QIDP and Fast Track Designations for Aemcolo (Rifamycin SV MMX<sup>®</sup>) for Travelers' Diarrhea**

Upon FDA Approval, Aries Pharmaceuticals, Inc. to Lead U.S. Commercial Efforts

**DUBLIN – October 30, 2017** – [Cosmo Pharmaceuticals N.V.](#) (SIX: COPN) today announced that the U.S. Food and Drug Administration (FDA) has granted both Qualified Infectious Disease Product (QIDP) and Fast Track designations for Aemcolo (Rifamycin SV MMX<sup>®</sup>) for the treatment of patients with travelers' diarrhea. [Aries Pharmaceuticals, Inc.](#), Cosmo's U.S. subsidiary based in San Diego, California, will lead the commercial sales and marketing for Aemcolo in the U.S.

"There have not been any new chemical entities approved to treat colonic infections in years, so resistance to current available drugs is a serious issue. The QIDP and Fast Track designations highlight the importance of treating colonic infections with new chemical entities and Aemcolo's potential to address this unmet medical need," said Alessandro Della Chà, Chief Executive Officer of Cosmo Pharmaceuticals. "We look forward to productive interactions with the FDA as we work to bring Aemcolo to patients."

"We are pleased with the FDA's decision to Fast Track Aemcolo and provide those who suffer from travelers' diarrhea with a potentially new treatment option," said Tom Joyce, CEO of Aries Pharmaceuticals. "Travelers' diarrhea can be highly disruptive and cause significant discomfort for patients, and in some cases, it can progress to more serious conditions if not treated effectively. Aemcolo has the potential to be an excellent fit with our portfolio of novel products that address high unmet needs for physicians and patients in diagnosing and treating gastrointestinal disorders."

If approved, Aemcolo will be eligible for an additional five years of market exclusivity based on the QIDP designation under the Generating Antibiotic Incentives Now (GAIN) Act. The GAIN Act is intended to encourage development of new antibiotic drugs for the treatment of serious or life-threatening infections. With Fast Track designation, Aemcolo is now eligible for priority review. Fast Track is a process the FDA designed to facilitate the development and expedite the review of new drugs that are intended to treat serious conditions and fill an unmet medical need. The program's purpose is to get important new drugs to the patient earlier.

Phase III clinical trials of Aemcolo in travelers' diarrhea have been completed in the U.S. and EU. The Phase III program demonstrated Aemcolo's superiority as compared to placebo (p-value= 0.0008) and its non-inferiority as compared to Ciprofloxacin.

New Drug and Marketing Authorization Applications are currently being prepared for submission to the FDA and European Medicines Agency, respectively.

Earlier this year, Aries launched [Eleview](#)<sup>™</sup>, a Cosmo-developed novel, ready-to-use submucosal injectable that forms an immediate and long-lasting cushion beneath lesions undergoing removal during colonoscopy. Cosmo and Aries also recently announced that the FDA assigned a Prescription Drug User Fee Act (PDUFA) date of May 21, 2018 for Methylene

Blue MMX<sup>®</sup>, being studied for the detection and visualization of pre-cancerous and cancerous lesions in people undergoing screening and surveillance colonoscopies.

### **About Aemcolo**

Aemcolo is a pharmaceutical product candidate employing rifamycin SV engineered with Cosmo Pharmaceuticals' MMX<sup>®</sup> technology. Aemcolo is a broad spectrum, semi-synthetic, orally administered, minimally absorbed antibiotic which can be used for the treatment of bacterial infections of the colon such as travelers' diarrhea. The application of MMX technology to rifamycin SV allows the antibiotic to be delivered directly into the colon, avoiding unwanted effects on the beneficial bacterial flora living in the upper portions of the gastro-intestinal tract. The specific dissolution profile of Aemcolo tablets is thought to increase the colonic disposition of the antibiotic so that an optimized intestinal concentration is achieved thus abating its systemic absorption in the small intestine.

### **About Cosmo Pharmaceuticals**

Cosmo is a specialty pharmaceutical company that aims to become a global leader in the field of optimized therapies for selected Gastrointestinal Disorders and Endoscopic Procedures. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as Ulcerative Colitis and Crohn's Disease, and Colon Infections. In addition, the Company has developed a medical device for polyp and adenoma excision and is has completed clinical trials of Methylene Blue MMX<sup>®</sup>, a diagnostic drug for the detection of colon cancer as well as new chemical entities that are being developed by the associate company Cassiopea S.p.A. for the topical treatment of skin diseases. Cosmo's MMX products that have reached the market are Lialda<sup>®</sup>/Mezavant<sup>®</sup>/Mesavancol<sup>®</sup>, a treatment for IBD that is licensed globally to Giuliani and Shire Limited and Uceris<sup>®</sup>, the first glucocorticosteroid indicated for the induction of remission in active, mild to moderate Ulcerative Colitis, licensed in US to Santarus/Salix/Valeant and in the Rest of the World to Ferring as Cortiment<sup>®</sup>. Cosmo's proprietary MMX technology is at the core of the Company's product pipeline and was developed from its expertise in formulating and manufacturing gastrointestinal drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. The technology is designed to deliver active ingredients in a targeted manner in the colon. For further information on Cosmo, please visit the Company's website: [www.cosmopharma.com](http://www.cosmopharma.com).

### **About Aries Pharmaceuticals, Inc.**

Aries Pharmaceuticals, Inc. (Aries) is a specialty pharmaceutical company commercializing best-in-class gastroenterology products for the United States market with a focus on products utilized in endoscopy and for the treatment of specific gastrointestinal diseases. The company's initial portfolio of four products, three of which are still in development, are licensed from Cosmo Pharmaceuticals N.V. to Aries Ltd. Aries is the US distribution arm of Aries Ltd., a wholly owned subsidiary of Cosmo Pharmaceuticals N.V. For further information on Aries, please visit the company's website: [www.ariespharma.com](http://www.ariespharma.com).

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