



FDA accepts New Drug Application for Methylene Blue MMX™ and sets PDUFA Date for May 21, 2018

SAN DIEGO - October 16, 2017 - [Aries Pharmaceuticals, Inc.](#) (Aries), a specialty pharmaceutical company commercializing best-in-class gastroenterology products, today announced that the U.S. Food and Drug Administration (FDA) has set a PDUFA date of May 21st, 2018, for its decision on the New Drug Application (NDA) for Methylene Blue MMX™ (MB MMX). A Phase III clinical trial studied Methylene Blue MMX™ for the detection and visualization of pre-cancerous and cancerous lesions in people undergoing screening and surveillance colonoscopies. MB MMX was developed by [Cosmo Pharmaceuticals, N. V.](#) and upon FDA approval, Aries will be the sole distributor of MB MMX in the United States.

“We are excited that the FDA has accepted the NDA submission, and our team is focused on preparing for the anticipated approval of MB MMX in the U.S.,” Aries CEO Tom Joyce stated. He added, “this milestone marks another positive step towards bringing innovative drugs to the GI community and strengthens the Aries gastrointestinal franchise.” In May of this year, Aries launched [Eleview™](#), a novel ready-to-use submucosal injectable that forms an immediate and long-lasting cushion beneath lesions undergoing removal during colonoscopy.

MB MMX™ is a first-in-class drug candidate based on Cosmo Pharmaceuticals’ proprietary MMX delivery technology. This formulation allows methylene blue to aid in the detection and visualization of adenomas during colonoscopy. In the Phase III clinical trial, MB MMX met its primary endpoint (p-value: 0.009), identifying 17.71% more patients with adenomas or carcinomas than HDWL (High Definition White Light) colonoscopy which is currently the most advanced standard of care. Adenomas were found in 56.3% of all subjects when using MB MMX, in contrast to 47.8% found with HDWL. The NDA is expected to demonstrate that MB MMX increases the Adenoma Detection Rate (ADR) beyond the current standard of care in endoscopic procedures. Results of the Phase III trial are expected to be published next year.

“Increases in ADR have important clinical relevance,” stated Michael B. Wallace MD, MPH, (Mayo Clinic Florida) and a primary investigator on the Phase III trial. He added that, “we know that for each 1% increase in ADR, a 3% decline in the incidence of interval cancer and a 5% decline in the incidence of fatal colorectal cancer (CRC) should be expected. MB MMX has the potential to provide gastroenterologists with a significant new means to improve their ADR and potentially help reduce colorectal cancer rates in the United States.”

About Colonoscopies and Colorectal Cancer

Colonoscopies are used for the early detection and prevention of colorectal cancer, one of the leading causes of cancer deaths in the United States.¹ The detection and removal of precancerous and cancerous lesions as a part of colorectal cancer screening colonoscopies are key to colorectal cancer prevention.² In fact, the U.S. Multi-Society Task Force of Colorectal Cancer has identified that the Adenoma Detection Rate (ADR) is an important quality measure^{3,4} and an independent predictor of the risk and interval cancer after screening colonoscopy.⁵ In a prospective study of individuals who underwent screening colonoscopy within a National Colorectal Cancer Screening Program, increased ADR was associated with a reduced risk of interval colorectal cancer and death.²

About MB MMX™

MB MMX is a novel application of methylene blue dye. MMX technology allows for the delivery of methylene blue along the entire length of the colon, with the objective to enable endoscopists to better detect and visualize pre-cancerous and cancerous lesions. MB MMX is formulated as a tablet that provides sustained dye contact with the mucosal wall as it travels through the colon, allowing the time needed to ensure its absorption in the cells lining the colon wall, thus enhancing contrast between abnormal areas and surrounding healthy cells before an endoscopy procedure is initiated.

About Eleview™

Eleview submucosal injectable composition is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device. Developed by Cosmo Pharmaceuticals, Eleview has been 510(k) cleared by the FDA as a class II medical device and is the only commercially available medical device for this indication. Additional product information at EleviewUS.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

References

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¹ U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2014 Incidence and Mortality Web-based Report. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute; 2017

² Kaminski MF, Wieszczy P, Rupinski M, et al. Increased Rate of Adenoma Detection Associates With Reduced Risk of Colorectal Cancer and Death. *Gastroenterology*. 2017;153(1):98-105.

³ Rex DK, Boland CR, Dominitz JA, et al. Colorectal cancer screening: Recommendations for physicians and patients from the U.S. Multi-Society Task Force on Colorectal Cancer. *Gastrointestinal endoscopy*. 2017;86(1):18-33.

⁴ Rex DK, Schoenfeld PS, Cohen J, et al. Quality indicators for colonoscopy. *Gastrointestinal endoscopy*. 2015;81(1):31-53.

⁵ Kaminski MF, Regula J, Kraszewska E, et al. Quality Indicators for Colonoscopy and the Risk of Interval Cancer. *New England Journal of Medicine*. 2010;362(19):1795-1803.