# Aries Pharmaceuticals, Inc. Shares Positive Results for Clinical Study of Eleview™ at Digestive Disease Week Annual Meeting

## *Effectiveness and Safety Positively Demonstrated Against Standard of Care; Convenient "Twist and Go" Packaging Unveiled*

**SAN DIEGO** - May 18, 2017 - Aries Pharmaceuticals, Inc. (Aries), a specialty pharmaceutical company commercializing best-in-class gastroenterology products, shared positive results of the first Eleview™ clinical trial in humans at the annual Digestive Disease Week (DDW) conference in Chicago, Illinois earlier this month. Eleview is a novel, ready to use, methylene blue containing, submucosal injectable composition for use in the easy and safe endoscopic removal of polyps, adenomas, and early stage cancers, and other lesions in the gastrointestinal (GI) tract.

The product, which is packaged as a set of five 10 mL single use, sterile ampoules with a luer lock closure that can easily be connected to a suitable syringe, was also unveiled for the first time. The "Twist and Go" ampoules enable endoscopists to quickly access Eleview when needed without having to wait for compounding and eliminate product waste should a lesion not be identified during the procedure. Eleview is administered through an endoscope via a normal, commercially available endoscopic injection needle.

The goals of the study were to assess the comparative effectiveness and safety of Eleview versus standard saline plus methylene blue (saline admixture) in patients undergoing Endoscopic Mucosal Resection (EMR) of colonic lesions ≥20 mm. While not powered for statistical significance, several efficacy endpoints did demonstrate significance and all others trended positively for Eleview.

**Study Results**

Data presented at the meeting positively demonstrated both efficacy and safety for Eleview when compared to saline plus methylene blue.

The three primary efficacy endpoints were all positive for the Eleview arm of the study:

- The mean total injected volume of Eleview needed per procedure for lesion removal was 16.1 mL (range of 3-41 mL) compared to the saline plus methylene blue arm which had a mean total injected volume of 31.6 mL (range of 4-248 mL). In the comparator arm, 49.2% more saline admixture was required than Eleview. Statistical significance ($P<0.001$) was achieved for this endpoint.
- The mean total injected volume per lesion was also less for Eleview with 0.53 mL per mm of lesion (range of 0.09-1.75 mL/mm) compared to saline admixture which needed a volume of 0.92 mL per mm (range of 0.2-4.96 mL/mm) and represents 42.4% more volume per mm needed of saline admixture than of Eleview. Statistical significance ($P<0.001$) was also achieved for this endpoint.
- Time to resect the lesion was notably lower for the Eleview arm of the study having a mean time of 19.15 minutes (range of 1-100 minutes) while the comparator arm required 35.5% longer with a mean of 29.7 minutes (range of 2-687 minutes) ($p=0.326$).

Secondary efficacy endpoints also demonstrated relative improvement for the Eleview arm of the study:

- Injected volume needed to provide initial lift per lesion with Eleview had a mean of 10.4 mL compared to saline plus methylene blue which had a mean of 15.3 mL ($p<0.001$).
- Less re-injections were necessary when using Eleview (1.05) than the comparator arm (1.79) ($p=0.159$).
- When Eleview was used, the lesions were removed in fewer number of pieces (11.9%; $p<0.052$).
- 58% more *en bloc* (removal in one piece) resections were possible with Eleview ($p<0.125$).
- The Sydney Resection Quotient (calculated by dividing the lesion size by the total number of resections (pieces) required to remove the lesion) was 28.8% higher in the Eleview arm ($p<0.044$).

The safety data is interim given that some patients have not yet reached their 60-day post-procedure follow-up exam. To date, no substantial differences in the number of complications between Eleview and the comparator saline admixture arm were seen. The study results so far suggest that Eleview is at least as safe as the comparator saline in terms of procedural complications.

“The results of this study helped to demonstrate clear procedural advantages over saline and that’s great news for patients and clinicians -- and potentially also the healthcare system,” noted David Kriesel, Executive Director of Medical Affairs. “A key differentiator for Eleview is the fact that it’s premixed and ready-to-use. Unlike the current standard of care of saline admixed with methylene blue and/or other components, Eleview’s convenient ready-mixed packaging can save procedure time by not having to order the admixture to be compounded either before or during the procedure. We’re excited to now offer the product in the United States, and look forward to working with endoscopists to increase access nationwide.”

The study helps to reinforce the benefits Eleview presents for gastroenterologists and patients. Upon injection, the product forms an immediate cushion of optimal shape, height, and duration. The inclusion of methylene blue, a contrast dye, improves visibility of the lesion. By providing an immediate and long-lasting cushion beneath the polyp and improving the visibility of the lesion, Eleview helps endoscopists achieve a complete and safe removal of the lesion. When compared to saline, one of the most commonly used agents and used as the comparator arm with the addition of methylene blue in the above study, Eleview demonstrated better cushion-forming ability and a duration of lift of up to 45 minutes. In addition to potential time savings gained from the premixed formulation and a more rapid lesion removal, costs savings may also be seen if there are shortened procedural times, which could also positively impact patient sedation time, endoscopy suite utilization, and personnel costs per procedure. Additional studies are being considered to confirm these assumptions.

**About the Study**

This first-in-human study was a randomized, double blind, multicenter clinical trial with parallel arms with sites in the United States and Europe. 211 patients were included in the primary analysis. The mean lesion size in the Eleview arm was 31.64 mm. In the comparator saline arm, the mean lesion size was 32.31 mm. The data set was presented at Digested Disease Week (DDW) on May 8, 2017 by one of the principal investigators, Dr. Douglas Rex from Indiana University Hospital, Indianapolis, Indiana. Additional principal investigators include: Mike Wallace from Mayo Clinic, Jacksonville, Florida; Prateek Sharma, University of Kansas Medical Center, Kansas City, Kansas; Alessandro Repici, Humanitas Research Hospital, Milan, Italy; and Pradeep Bhandari, Solent Center for Digestive Diseases, Portsmouth, United Kingdom. The clinical trial was sponsored by Cosmo Pharmaceuticals, N.V. (SIX: COPN) (Cosmo), the developer of Eleview.

**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, Eleview has been 510(k) cleared by the FDA as a class ll medical device and is the only commercially available medical device for this indication. Additional product information at EleviewUS.com. Eleview is available now for order at 888-ARIES-08.

**Important Safety Information**

**WARNINGS AND PRECAUTIONS**

- **The safety of Eleview has not been established in pregnant or lactating women, or in children under 18 years of age.**
- **The endoscopist injecting Eleview must be experienced in the injection technique.**

**CONTRAINDICATIONS**
**Patients with known sensitivity to any of the components contained in Eleview.**

**ADVERSE REACTIONS**

- **Rarely, local bleeding and/or inflammatory reaction could occur which may or may not be associated with Eleview.**

**Please see Instructions for Use for complete Important Safety Information.**

**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.aries-pharma.com

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