CLINICAL DATA UPDATE:

A randomized, double-blind, comparative effectiveness and safety study of Eleview™ for EMR* of large sessile polyps of the colon

Eleview™—a new commercially available submucosal injectable composition

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**INDICATION**

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.

*Endoscopic mucosal resection*
First Eleview™ in-human study: A multicenter trial at select sites in the US and EU

Method
A post-approval, randomized, double-blind trial comparing the effectiveness and safety of submucosal injection with Eleview™ vs. sites’ standard of care was performed in patients undergoing endoscopic EMR of treatment-naïve polyps or adenomas of the colon ≥ 20 mm.

Population: 211 patients undergoing EMR for excision of treatment-naïve, laterally spreading sessile or flat colonic polyps/adenomas ≥ 20 mm in largest dimension

- 119 males total
- 92 females total

Eleview™ (n=102)
Comparator (n=109): Sites’ standard of care: A mixture of normal saline and methylene blue

Average patient age
- 65.8 years Eleview™ group
- 66.2 years Comparator group

Breakdown by gender
- 119 males total
- 92 females total

Summary
The study demonstrated relative improvement with Eleview™ over saline plus methylene blue for all primary and secondary efficacy measures.

- While the study was not powered to show statistical significance, several endpoints were statistically significant in favor of Eleview™.

An interim analysis showed no difference in the number of adverse events between Eleview™ and the comparator.

Primary endpoints
- Efficacy:
  - Total injected volume needed to complete the EMR procedure
  - Total injected volume per lesion size
  - Time to resect the lesion completely
- Safety:
  - Complication and adverse event occurrence during and after the procedure

Secondary endpoints were also explored
Eleview™ demonstrated relative improvement for all primary endpoints

Total injected volume needed to complete the resection (mean mL)

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<thead>
<tr>
<th></th>
<th>Saline with methylene blue</th>
<th>Eleview™</th>
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<tbody>
<tr>
<td>Total volume</td>
<td>31.6</td>
<td>16.1</td>
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49.2% less volume
Significantly lower with Eleview™
P < 0.001

Total injected volume needed per lesion size (mean mL/mm)

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<th>Saline with methylene blue</th>
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<tr>
<td>Total volume</td>
<td>0.92</td>
<td>0.535</td>
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42.4% less volume
Significantly lower with Eleview™
P < 0.001

Time to resect the lesion (minutes)

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<th>Eleview™</th>
<th>Saline with methylene blue</th>
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<tr>
<td>Total time</td>
<td>19.15</td>
<td>29.70</td>
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35.5% less time
Potential time savings with Eleview™
P = 0.326

1 Significantly lower with Eleview™
P < 0.001
**Safety: No differences in the number of adverse events**

In the interim analysis, adverse events were essentially identical and rare.\(^1\)

Subjects with at least one complication: **Eleview™ 17** (15.0%) **Comparator 17** (15.2%).\(^1\)

**Note:** This data is interim until final patient analysis is completed after the 60-day postprocedure follow-up period.

**Eleview™ demonstrated relative improvement for all secondary endpoints\(^1\)**

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**Number of resection pieces\(^1\)**

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<th>Eleview™</th>
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<td></td>
<td>6.5</td>
<td>5.7</td>
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**11.9% fewer pieces**

Difference favored Eleview™

*P*=0.052

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**Sydney Resection Quotient (SRQ)\(^1\)**

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<td></td>
<td>8.0</td>
<td>10.3</td>
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**Greater SRQ**

Size of each resection piece was significantly greater with Eleview™

*P*=0.044

SRQ is calculated by dividing the lesion size (in mm) by the number of resections required to remove the lesion.
Additional secondary endpoints demonstrated relative improvement with Eleview™\textsuperscript{1,2}

Eleview™ demonstrated a positive trend toward time savings with an 11.2% reduction to complete the entire procedure using Eleview™ vs the comparator.\textsuperscript{2}

Ease of use: Equal to current standard\textsuperscript{1}

On a 5-point scale, investigators found Eleview™ as easy to use as the comparator.\textsuperscript{1}
**Eleview™: Ready-to-use submucosal injection agent with methylene blue**

**Designed for safe and easy resection procedures**
- Provides an immediate and long-lasting cushion that holds for up to 45 minutes
- Contains methylene blue to improve visibility of lesion margins
- Designed to lower the risk of perforation
- Designed for use via a normal, commercially available endoscopic injection needle*
- Sterile and ready to use
- FDA 510(k) cleared as a medical device

*Injection needle not provided as part of Eleview™.

**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 administration technique.

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

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

For more information about Eleview™, including Instructions for Use, visit EleviewUS.com.