Barhemsys® (amisulpride) – New drug approval

- On February 27, 2020, Acacia Pharma announced the FDA approval of Barhemsys (amisulpride), in adults for the prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class and for the treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.

- PONV is a common complication of surgery, occurring in approximately 30% of surgical patients and up to 80% of high-risk patients. Approximately 65 million surgical procedures are conducted in the U.S. each year that are eligible for antiemetic use to prevent PONV.

- Barhemsys is a selective dopamine-2 (D2) and D3 receptor antagonist.

- The efficacy of Barhemsys for the prevention of PONV was evaluated in two randomized, double-blind, placebo-controlled studies in patients undergoing general anesthesia and elective surgery. In study 1, 342 patients received Barhemsys monotherapy. In study 2, 1,147 patients received Barhemsys in combination with one other intravenously (IV) administered, non-dopaminergic antiemetic (ondansetron, dexamethasone or betamethasone). The primary efficacy endpoint in both trials was complete response (CR), defined as absence of any episode of emesis or use of rescue medication within the first 24 hours postoperatively.

- In study 1, CR was seen in 44% of Barhemsys treated patients vs. 33% of placebo treated patients (treatment difference = 12%; 95% CI: 2, 22).
- In study 2, CR was seen in 58% of Barhemsys treated patients vs. 47% of placebo treated patients (treatment difference = 11%; 95% CI: 5, 17).

- The efficacy of Barhemsys for the treatment of PONV was evaluated in two randomized, double-blind, placebo-controlled studies in patients experiencing PONV after general anesthesia and elective surgery. In study 3, 369 patients who had not received prior PONV prophylaxis received a single Barhemsys 10 mg dose. In study 4, 465 patients who had received and failed PONV prophylaxis with an antiemetic of another class were treated with a single 10 mg dose of Barhemsys. The primary efficacy endpoint was CR, defined as absence of any episode of emesis or use of rescue medication within the first 24 hours after treatment (excluding emesis within the first 30 minutes).

- In study 3, CR was seen in 31% of Barhemsys treated patients vs. 22% of placebo treated patients (treatment difference = 10%; 95% CI: 1, 19).
- In study 4, CR was seen in 42% of Barhemsys treated patients vs. 29% of placebo treated patients (treatment difference = 13%; 95% CI: 5, 22).

- A warning and precaution of Barhemsys is QT prolongation.

- The most common adverse reactions (≥ 2%) with Barhemsys use for the prevention of PONV were increased blood prolactin concentrations, chills, hypokalemia, procedural hypotension, and abdominal distension, and for the treatment of PONV: infusion site pain.

- The recommended dose of Barhemsys is shown in the table below:

Indication	Dosage Regimen
Prevention	5 mg as a single IV injection infused over 1 to 2 minutes at the time of

Continued . . .

of PONV	induction of anesthesia
Treatment of PONV	10 mg as a single IV injection infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure

- Acacia Pharma plans to launch Barhemsys in the second half of 2020. Barhemsys will be available as a 5 mg/2 mL solution in a single dose vial.