Adlarity® (donepezil) – New drug approval

- On March 14, 2022, Corium announced the FDA approval of Adlarity (donepezil), for the treatment of mild, moderate, and severe dementia of the Alzheimer's type.

- Adlarity, an acetylcholinesterase inhibitor, is the first transdermal formulation of donepezil. It is also available generically as a tablet and as an orally disintegrating tablet (ODT).

- The efficacy of Adlarity is based on a relative bioavailability study in healthy subjects comparing Adlarity transdermal system to Aricept tablets.

- Adlarity is contraindicated in patients with known hypersensitivity to donepezil or to piperidine derivatives and patients with a history of allergic contact dermatitis with use of Adlarity.

- Warnings and precautions for Adlarity include application site skin reactions; use during anesthesia; cardiovascular conditions; nausea and vomiting; peptic ulcer disease and gastrointestinal bleeding; genitourinary conditions; neurological conditions (seizures); and pulmonary conditions.

- The most common adverse reactions (> 5% with donepezil tablets and twice the placebo rate) were nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue, and anorexia.

- The recommended starting dosage of Adlarity is 5 mg/day. After 4 to 6 weeks, the dosage may be increased to the maximum recommended dosage of 10 mg/day. Adlarity should be administered as one transdermal system applied to the skin once weekly. Doses of the transdermal system higher than the 10 mg/day equivalent have not been evaluated.

    — Refer to the Adlarity drug label for instructions for switching to Adlarity from donepezil tablets or ODT.

- Corium plans to launch Adlarity in early Fall 2022. Adlarity will be available as a 5 mg/day and 10 mg/day transdermal system.