Lodoco® (colchicine) – New drug approval

- On June 20, 2023, Agepha Pharma announced the FDA approval of Lodoco (colchicine), to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular (CV) death in adult patients with established atherosclerotic disease or with multiple risk factors for CV disease.

- Lodoco is the first colchicine formulation approved for CV disease.

    — Other colchicine formulations are available generically and approved for gout and familial Mediterranean fever.

- The efficacy of colchicine in patients with CV events is derived from published literature (LoDoCo2) along with other supportive studies. LoDoCo2 was an investigator-initiated, randomized, placebo controlled, double-blind, event-driven study in 5,522 patients with stable coronary artery disease. Patients received Lodoco or placebo. The primary endpoint was a composite of CV death, spontaneous (nonprocedural) MI, ischemic stroke, or ischemia-driven coronary revascularization.

    — Treatment with colchicine resulted in a 31% lower relative risk of the primary composite endpoint events compared to placebo (hazard ratio 0.69, 95% CI: 0.57, 0.83; $p < 0.001$) and the number needed to treat was 36.

- Lodoco is contraindicated in patients with:

    — Concurrent use of strong CYP3A4 inhibitors or P-glycoprotein inhibitors
    — Renal failure and severe hepatic impairment
    — Pre-existing blood dyscrasias and in patients hypersensitive to this drug or any inactive ingredient of Lodoco.

- Warnings and precautions for Lodoco include blood dyscrasias and neuromuscular toxicity.

- The common side effects reported in published clinical studies and literature with the use of colchicine are gastrointestinal symptoms (diarrhea; vomiting; abdominal cramping) and myalgia.

- The recommended dose of Lodoco is 0.5 mg orally once daily.

- Agepha Pharma plans to launch Lodoco in the second half of 2023. Lodoco will be available as a 0.5 mg tablet.