Thiola® EC (tiopronin) – New formulation approval

- On June 28, 2019, Retrophin announced the FDA approval of Thiola EC (tiopronin) delayed-release tablets, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone.

- Previously, tiopronin (Thiola®) was approved as 100 mg tablets for the same indication as Thiola EC.

    — Thiola is administered one hour before or two hours after a meal.

- Thiola EC allows for administration with or without food. Additionally, there is a potential to reduce the number of tablets needed to manage cystinuria.

- Warnings and precautions of Thiola EC include proteinuria and hypersensitivity reactions.

- The most common adverse reactions (≥ 10%) with Thiola EC use were nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.

- The recommended initial dose of Thiola EC in adult patients is 800 mg/day administered orally in three divided doses at the same times each day, with or without food.

    — In clinical studies, the average dosage was about 1,000 mg/day.
    — Thiola EC dosage should be adjusted to maintain urinary cystine concentration < 250 mg/L.
    — The recommended initial dosage in pediatric patients weighing ≥ 20 kg is 15 mg/kg/day.
    — Dosages > 50 mg/kg per day in pediatric patients should be avoided.

- Retrophin plans to launch Thiola EC in July 2019. Thiola EC will be available in 100 mg and 300 mg enteric-coated tablets.