Accrufer® (ferric maltol) – New drug approval

- On July 26, 2019, Shield Therapeutics announced the FDA approval of Accrufer (ferric maltol), for the treatment of iron deficiency in adults.

- Accrufer is an oral non-salt iron replacement product.

- The efficacy of Accrufer was established in two studies (AEGIS 1 and AEGIS 2) in 128 patients with iron deficiency anemia and inflammatory bowel disease. Patients were randomized to receive Accrufer or a placebo for 12 weeks. The major efficacy outcome was the mean difference in hemoglobin (Hb) concentration from baseline to week 12 between Accrufer and placebo.

    — The least square (LS) mean difference in the change from baseline in Hb concentration between Accrufer and placebo was 2.18 g/dL ($p < 0.0001$).

- The efficacy of Accrufer was also evaluated in the AEGIS 3 study in 167 patients with iron deficiency anemia and non-dialysis dependent chronic kidney disease. Patients were randomized to receive either Accrufer or placebo for 16 weeks. The major efficacy outcome was the mean difference in Hb concentration from baseline to week 16 between Accrufer and placebo.

    — The LS mean difference in the change from baseline in Hb concentration between Accrufer and placebo was 0.52 g/dL ($p = 0.0149$).

- Accrufer is contraindicated in patients with a history of:

    — Hypersensitivity to the active substance or to any of the excipients.
    — Hemochromatosis and other iron overload syndromes. Use may result in iron overdose.
    — Receiving repeated blood transfusions. Use may result in iron overload.

- Warnings and precautions for Accrufer include increased risk of inflammatory bowel disease flare, iron overload, and risk of overdosage in children due to accidental ingestion.

- The most common adverse reactions (> 1%) with Accrufer use were flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension.

- The recommended dosage of Accrufer is 30 mg twice daily, taken 1 hour before or 2 hours after a meal.

    — Treatment duration will depend on the severity of iron deficiency but generally at least 12 weeks of treatment is required. The treatment should be continued as long as necessary until ferritin levels are within the normal range.

- Shield Therapeutics launch plans for Accrufer are pending. Accrufer will be available as a 30 mg capsule.