Imkeldi (imatinib) – New drug approval

- On November 22, 2024, the FDA approved Shorla Oncology's Imkeldi (imatinib) oral solution.
- Imatinib is available as an oral tablet under the brand name Gleevec® and its generic alternatives.
- The indications for Imkeldi mirror those of Gleevec (10 approved indications). Refer to the Imkeldi drug label for a complete list of the indications for use.
- Warnings and precautions for Imkeldi include fluid retention and edema; hematologic toxicity; congestive heart failure and left ventricular dysfunction; hepatotoxicity; hemorrhage; gastrointestinal disorders; hypereosinophilic cardiac toxicity; dermatologic toxicities; hypothyroidism; embryo-fetal toxicity; growth retardation in children and adolescents; tumor lysis syndrome; impairments related to driving and using machinery; renal toxicity; and measuring device.
- The most common adverse reactions (≥ 30%) with Imkeldi use were edema, nausea, vomiting, muscle cramps, musculoskeletal pain, diarrhea, rash, fatigue, and abdominal pain.
- Refer to the Imkeldi drug label for complete dosing and administration recommendations across its various indications.
- Sharla Oncology's launch plans for Imkeldi are pending. Imkeldi will be available as a 80 mg/mL oral solution.