Tiglutik™ (riluzole) – New orphan drug approval

- On September 6, 2018, ITF Pharma announced the FDA approval of Tiglutik (riluzole), for the treatment of amyotrophic lateral sclerosis (ALS).
- ALS is a progressive, ultimately fatal neurodegenerative disease, marked by a gradual degeneration of nerve cells of the central nervous system that control voluntary muscle movement. A little over 5,000 people in the U.S. are diagnosed with ALS each year. It is estimated that more than 20,000 Americans have the disease at any given time.
- Tiglutik is the first easy-to-swallow thickened riluzole liquid for ALS.
- Riluzole is also available as brand (Rilutek®) and generic tablets for the treatment of ALS.
- The efficacy of Tiglutik is based upon bioavailability studies comparing oral riluzole tablets to Tiglutik oral suspension.
- Warnings and precautions of Tiglutik include hepatic injury, neutropenia, and interstitial lung disease.
- The most common adverse reactions (≥ 5% and > placebo) with Tiglutik use were oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain.
- The recommended dosage of Tiglutik is 50 mg (10 mL) taken orally twice daily, every 12 hours.
    - Measure serum aminotransferases before and during treatment with Tiglutik.
- ITF Pharma plans to launch Tiglutik in mid-October of 2018. Tiglutik will be available as a 50 mg/10 mL oral suspension.