



## **ITF PHARMA ANNOUNCES FDA APPROVAL OF TIGLUTIK™ (RILUZOLE) ORAL SUSPENSION FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)**

*~ TIGLUTIK, the First and Only Easy-to-Swallow Thickened Riluzole Liquid for ALS, will be Commercially Available Mid-October of 2018 ~*

*~ TIGLUTIK Oral Suspension Eases Administration, Fulfilling Therapeutic Need for Approximately 80 Percent of ALS Patients Who Develop Swallowing Impairment, or Dysphagia ~*

**Berwyn, Pa., Sept. 6, 2018** – ITF Pharma, a U.S.-based specialty pharmaceutical company and a subsidiary of Italfarmaco, a privately-held European specialty pharmaceutical company, committed to investing in and commercializing impactful medicines in therapeutic areas with unfulfilled needs, announced today that the U.S. Food and Drug Administration (FDA) has approved TIGLUTIK™ (riluzole) oral suspension for the treatment of amyotrophic lateral sclerosis (ALS). TIGLUTIK is the first and only easy-to-swallow thickened riluzole liquid for ALS and is administered twice daily via an oral syringe.

“Having a therapeutic option designed to specifically overcome the challenges of disease-related dysphagia in ALS is a welcome step forward for the many doctors, caregivers and people living with ALS who have relied on riluzole as the gold standard of treatment for more than 20 years to slow the progression of this devastating disease,” said Hiroshi Mitsumoto, MD, DSc, Wesley J. Howe professor of neurology at Columbia University at The Neurological Institute of New York and New York-Presbyterian Hospital/Columbia University Medical Center. “The availability of TIGLUTIK oral suspension precludes the need for manipulation of tablets by patients or caregivers, easing administration and may provide an opportunity for more accurate dosing and enhanced patient compliance.”

“This approval marks an important step forward in the treatment of ALS. The ALS Association would like to thank the FDA and ITF Pharma for working together to bring this important new formulation of riluzole to the ALS community,” said Calaneet Balas, president and chief executive officer at The ALS Association.

“We are very pleased with the FDA approval of TIGLUTIK and we look forward to making the first and only easy-to-swallow thickened riluzole liquid for ALS commercially available in the U.S. in mid-October through our highly-specialized field sales team,” said Denny Willson, chief executive officer of ITF Pharma. “ITF is committed to supporting the ALS community and to helping people

living with ALS find affordable access to TIGLUTIK. Therefore, we have partnered with a specialty pharmacy to create a simple and straightforward product support program that will help patients receive TIGLUTIK quickly and with ease. This reflects our underlying mission to provide valuable therapeutic options and support programs that make a positive difference in the lives of both patients and healthcare providers.”

Paolo Bettica, MD, PhD, vice president, research and development of Italfarmaco, commented: “This is the seventh approval worldwide for TIGLUTIK and a very significant advance for ITF Pharma and Italfarmaco. We are pleased to bring this new therapeutic option to ALS patients in the United States.”

The approval of TIGLUTIK is based on bioavailability studies comparing oral riluzole tablets to TIGLUTIK oral suspension. The most common side effects of TIGLUTIK are consistent with the established clinical profile of riluzole and include oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension and abdominal pain. While riluzole's mechanism of action is not fully understood, in clinical studies it has been shown repeatedly to modulate glutamate neurotransmission by inhibiting both glutamate release and postsynaptic glutamate receptor signaling.

TIGLUTIK has received orphan drug designation from the FDA.

### **About Amyotrophic Lateral Sclerosis (ALS)**

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig’s disease, 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.<sup>i</sup> According to the ALS Association and based on U.S. population studies, 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. The incidence of ALS increases with age, typically starting in the 40s and continuing until around the age of 80. However, ALS can occur in people in their 20s and 30s.<sup>ii</sup> In ALS, the degeneration of motor neurons is characterized by muscle weakness, typically impacting arms and legs, speech, swallowing and breathing. Impairment of swallowing (dysphagia) is a feature of ALS resulting from weakness or spasticity of muscles affecting the tongue, lips, palate, jaw, pharynx, larynx and upper trunk.<sup>1</sup>

### **About TIGLUTIK™ (riluzole) Oral Suspension**

TIGLUTIK™ (riluzole) oral suspension is indicated for the treatment of amyotrophic lateral sclerosis (ALS). TIGLUTIK is the first and only easy-to-swallow thickened riluzole liquid for ALS, and is administered orally twice-daily via a syringe. In clinical studies, the most common side effects of TIGLUTIK were oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain. These are not all of the possible side effects that you may experience with TIGLUTIK. Talk to your doctor if you have any symptoms that bother you or do not go away.

### **Indication**

TIGLUTIK (riluzole) is a prescription medicine for the treatment of amyotrophic lateral sclerosis (ALS).

### **Important Safety Information**

- You should not take TIGLUTIK if you are allergic to any of its ingredients.
- TIGLUTIK can cause liver injury, including death. Your doctor should do blood tests to check your liver function before and during your treatment and may stop treatment with TIGLUTIK if liver function is not normal. Contact your doctor immediately if you have unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine
- Call your doctor immediately if you have a fever, cough, or difficulty in breathing while taking TIGLUTIK.
- If you miss or skip a dose of TIGLUTIK, do not take any extra doses to make up for those you missed, but take your prescribed dose at the next regularly scheduled time.
- The most common side effects of TIGLUTIK that occurred during medical studies were numbness/tingling around the mouth, weakness, nausea, decreased lung function, high blood pressure, and abdominal pain. If any side effects become troublesome, contact your doctor.
- Be sure to tell your doctor and pharmacist about all other health conditions you have and all medicines you are taking, including nonprescription products and vitamins. If you have questions, please talk to your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-332-1088.

[Please click here for the full Prescribing Information.](#)

### **About ITF Pharma**

ITF Pharma ([www.itfpharma.com](http://www.itfpharma.com)) is a Pennsylvania-based, specialty pharmaceutical company committed to investing in and commercializing impactful medicines in therapeutic areas with unfulfilled needs. ITF Pharma is the U.S. subsidiary of Italfarmaco, a privately held European specialty pharmaceutical company engaged in the development of new and groundbreaking therapies. ITF's commercial portfolio includes TIGLUTIK™ (riluzole) oral suspension, the first and only thickened liquid formulation of riluzole, approved for the treatment of amyotrophic lateral sclerosis (ALS) by the U.S. Food and Drug Administration in September of 2018.

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<sup>i</sup> AM Dyer and A Smith. [Riluzole 5 mg/mL oral suspension: for optimized drug delivery in amyotrophic lateral sclerosis](#). *Drug Des Devel Ther.* 2017; 11: 59–64.

<sup>ii</sup> ALS Association. About ALS; [Facts You Should Know](#); last accessed August 28, 2018