



ITF PHARMA RECEIVES PATIENT IMPACT AWARD FOR FIRST AND ONLY EASY-TO SWALLOW THICKENED LIQUID TREATMENT FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Berwyn, Pa., Feb. 28, 2019 – 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 Company has been selected for the 2018 Patient Impact Award by Life Sciences Pennsylvania (LSPA). LSPA's annual Patient Impact Awards honor companies or organizations that have made significant contributions to the quality of healthcare or length of life of patients.

ITF is being recognized for the U.S. launch of TIGLUTIK™ (riluzole), the first and only easy-to-swallow thickened riluzole liquid for the treatment of amyotrophic lateral sclerosis (ALS). Approximately 80 percent of people with ALS develop difficulty swallowing, or dysphagia, because of gradual weakness and paralysis in the muscles of the face and throat. The availability of an FDA-approved 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.

"We are honored to be a recipient of the 2018 Patient Impact Award for the development and launch of TIGLUTIK, an important therapeutic advance for those experiencing disease-related dysphagia in ALS," said Peter Cook, chief operating officer of ITF Pharma. "We look forward to accepting this award alongside a tremendous representation of our life sciences colleagues here in Pennsylvania, and to continuing our unwavering support of the ALS community."

LSPA will present ITF with the award during the organization's annual dinner on March 13, 2019, at the Pennsylvania Convention Center.

"The recent availability of an easy-to-swallow formulation of riluzole marked an important step forward for people living with ALS, caregivers, and medical professionals," said Calaneet Balas, president and chief executive officer at The ALS Association. "ITF has been a committed partner to the ALS community and we look forward to continued collaboration on educational and support initiatives in 2019."

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. [To learn more, visit TIGLUTIK.com.](https://www.tiglutik.com)

TIGLUTIK was approved under FDA fast-track designation, which expedites the review of drugs that have the potential to treat serious conditions and fill an unmet medical need. 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.ⁱ 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.ⁱⁱ 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.¹

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, or call 1-800-332-1088.

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

About ITF Pharma

ITF Pharma (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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ⁱ 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.

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