

Company Announcement



ITF Therapeutics LLC Announces Appointment of Erica L. Monaco, CPA, as Chief Operating Officer

CONCORD, Mass., December 4, 2024 – ITF Therapeutics LLC, the U.S. affiliate of Italfarmaco, today announced the appointment of Erica L. Monaco, CPA, as chief operating officer. Bringing nearly two decades of experience in the pharmaceutical and financial sectors, Erica will oversee a broad range of strategic and operational functions.

“Since the establishment of ITF Therapeutics in January 2024, we have worked diligently to build a highly skilled and mission-driven team of functional experts who share a passion for serving rare disease communities. We are very pleased to welcome Erica to ITF Therapeutics during this exciting time following the U.S. FDA approval and successful commercial launch of DUVYZAT™ (givinostat) for the treatment of Duchenne muscular dystrophy (DMD),” said Matt Trudeau, President, ITF Therapeutics. “Erica’s deep financial and operational experience equips her to play a critical leadership role in ensuring we operate efficiently, effectively, and compliantly as we work to deliver on our commitments to the rare disease communities that we serve.”

Erica most recently served as chief operating officer at Medicus Pharma Ltd. Prior to joining Medicus Pharma, she held several leadership positions at Biofrontera Inc., including chief executive officer, chief financial officer, and chief operating officer. During her tenure, Erica helped secure multiple rounds of funding to support company growth, led the company through a successful IPO, and created the U.S. infrastructure to enable the commercial launch of a novel therapy for the treatment of actinic keratosis skin lesions. She also held a senior position at SUN Pharmaceuticals, Inc., where she oversaw reporting and accounting for two of the company’s subsidiaries. Erica started her career in public accounting, tax consulting, and financial planning at Deloitte and the WGBH Educational Foundation. She holds a master’s degree and a bachelor’s degree in accounting from the Isenberg School of Management at the University of Massachusetts Amherst. She is also a licensed CPA in Massachusetts.

“I am thrilled to join ITF Therapeutics at this pivotal time for the company. It is an honor to work with an amazing team of dedicated operations professionals to ensure we deliver on today’s operational needs and that we are positioned for growth and even greater impact in the years ahead,” said Erica L. Monaco, Chief Operating Officer, ITF Therapeutics.

About DUVYZAT™ (givinostat)

DUVYZAT is a U.S. FDA-approved histone deacetylase (HDAC) inhibitor indicated for the treatment of patients six years of age and older with Duchenne muscular dystrophy (DMD) that was discovered through the research and development efforts of Italfarmaco in collaboration with Telethon and Duchenne Parent Project (Italy). HDACs are enzymes located in the body’s cells that play a key role in maintaining and repairing muscles. In DMD, the HDAC enzymes become overactive, leading to chronic muscle inflammation, decreased muscle repair, and replacement of muscle with fat and scar tissue. DUVYZAT inhibits HDAC overactivity and is thought to help reduce inflammation, increase the body’s ability to repair muscles, and slow muscle loss. For more information visit www.DUVYZAT.com.



ITF Therapeutics LLC
300 Baker Avenue, Suite 280
Concord, MA 01742
www.itftherapeutics.com

Italfarmaco
www.italfarmaco.com

C-DUV-US-0160 12/2024

Company Announcement



About ITF Therapeutics LLC

ITF Therapeutics was launched in January 2024 as the U.S. affiliate of Italfarmaco focused on the development and commercialization of products to treat rare diseases. Building on a legacy grounded in collaboration and innovation, ITF Therapeutics strives to partner with leaders from the patient advocacy and treatment communities to ensure that our programs reflect and support their unique needs and goals. The establishment of ITF Therapeutics reflects Italfarmaco's goal to build a world-class team of experts who share a passion to make a positive impact for rare disease communities. For more information visit www.ifftherapeutics.com.

About Italfarmaco

Founded in 1938 in Milan, Italy, Italfarmaco is a private global pharmaceutical company that has led the successful development and approval of many pharmaceutical products around the world. The Italfarmaco group has operations in more than 90 countries through directly controlled or affiliated companies. The company is a leader in pharmaceutical research, product development, production, and commercialization with proven success in many therapeutic areas including immuno-oncology, gynecology, neurology, cardiovascular disease, and rare diseases. Italfarmaco's rare disease unit includes programs in Duchenne muscular dystrophy, Becker muscular dystrophy, amyotrophic lateral sclerosis, and polycythemia vera. For more information visit www.italfarmaco.com.

Indication and Important Safety Information

What is DUVYZAT?

DUVYZAT is a prescription medicine that is used for the treatment of Duchenne muscular dystrophy (DMD) in people 6 years of age and older.

It is not known if DUVYZAT is safe and effective in children under 6 years of age.

Important Safety Information

What is the most important information I should know about DUVYZAT?

- **Low platelet counts in your blood (thrombocytopenia).** Platelets are important for blood clotting, and a decrease in their numbers can lead to an increased risk of bleeding or bruising. Your healthcare provider will check your blood count before you start DUVYZAT and regularly during treatment for any signs of thrombocytopenia. Call your healthcare provider right away if you notice any unusual bleeding or small red or purple spots on the skin called petechiae. Your healthcare provider may change your dose of DUVYZAT if your blood platelet counts continue to be low or may stop your treatment with DUVYZAT.



ITF Therapeutics LLC
300 Baker Avenue, Suite 280
Concord, MA 01742
www.ifftherapeutics.com

Italfarmaco
www.italfarmaco.com

C-DUV-US-0160 12/2024

Company Announcement



- **Increased levels of fat (triglycerides) in your blood.** You may not have any symptoms, so your healthcare provider will do blood tests before you start DUVYZAT and regularly during treatment to check your triglyceride levels. Your healthcare provider may change your dose of DUVYZAT if your triglyceride levels continue to be high or may stop your treatment with DUVYZAT.
- **Frequent watery loose stools (diarrhea) and vomiting.** DUVYZAT can cause vomiting and moderate to severe diarrhea. If diarrhea occurs, you should keep track of the frequency and severity of your diarrhea symptoms, drink plenty of fluids, and contact your healthcare provider. Your healthcare provider may change your dose of DUVYZAT if the diarrhea cannot be managed or does not go away. Your healthcare provider may also stop your treatment with DUVYZAT.

Before taking DUVYZAT, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems or if you take any medicines that could increase your chance for irregular heart rhythms.
- have any bleeding problems.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking DUVYZAT with certain other medicines may affect each other. Taking DUVYZAT with other medicines can cause serious side effects. Do not start or stop other medicines without talking to your healthcare provider.

DUVYZAT can cause serious side effects, including:

- **See “What is the most important information I should know about DUVYZAT?”**
- **Changes in the electrical activity of your heart called QT Prolongation.** QT Prolongation can increase the risk of developing a type of irregular heart rhythm known as Torsades de Pointes. Call your healthcare provider right away if you feel faint, have an irregular heartbeat, feel dizzy, or lose consciousness.

The most common side effects of DUVYZAT included diarrhea, nausea, vomiting, stomach pain, low platelet counts in the blood, increased fat level in the blood, and fever.

These are not all of the possible side effects of DUVYZAT. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see [full Prescribing Information](#) and [Medication Guide](#)

DUVYZAT is a registered trademark of Italfarmaco S.p.A.



ITF Therapeutics LLC
300 Baker Avenue, Suite 280
Concord, MA 01742
www.itftherapeutics.com

Italfarmaco
www.italfarmaco.com

C-DUV-US-0160 12/2024

Company Announcement



U.S.A.

Media inquiries: Brian Connor | +1 212 253 8881 | bconnor@berrypr.com

Other inquiries: Patient Advocacy and Communications Lead U.S.A. | c.allen@itftherapeutics.com

Global

Media inquiries: Charlotte Spitz or Jacob Verghese | +49 (0)151 7441 6179 | italfarmaco@trophic.eu

Other inquiries: Patient Advocacy and Communications Lead | s.parker@italfarmaco.com

C-DUV-US-0160 12/2024



ITF Therapeutics LLC
300 Baker Avenue, Suite 280
Concord, MA 01742
www.itftherapeutics.com

Italfarmaco
www.italfarmaco.com

C-DUV-US-0160 12/2024