

PRESS RELEASE

Tolera Therapeutics files IND application for TOL101, appoints O'Toole to lead clinical operations

Kalamazoo, Michigan, Tuesday, Nov. 3, 2009 – Tolera Therapeutics, Inc., announced it has filed an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) for its lead candidate, TOL101, for prophylaxis of acute rejection of solid organ transplantation. TOL101 is a novel biologic protein that is designed to safely and specifically target T cells, components of the immune system that play a key role in the rejection, and ultimate failure, of transplanted organs. Organ transplantation is often the only viable treatment for many end-stage organ diseases.

“We are extremely pleased with our progress toward bringing TOL101 to the clinic.” commented John J. Puisis, President and CEO of Tolera. “This action marks an important development milestone as the company continues its drive to address the patient’s need for safer and more effective immune suppression therapy. Current industry practices and pipelines offer limited and incomplete solutions to advance patient care and meet this critical need. Pending acceptance by the FDA, we intend to conduct clinical studies starting in 2010.”

Tolera also announced the appointment of Leslie O'Toole to lead its clinical operations as Director, Clinical Programs. O'Toole brings over 20 years of industry experience with 16 years focusing on clinical research management. Mr. Puisis added “We’re excited about adding Leslie to our dynamic team. Her depth of clinical research experience adds an important operating aspect to the organization and positions us for continued success.” Prior to joining the company, O'Toole was Director, Project Management at Clinimetrics, a full service contract research organization where she was involved in over 35 studies researching drugs in numerous indications with a primary focus in oncology and immunology.

About Tolera Therapeutics: Tolera Therapeutics is a Kalamazoo, Michigan based biotechnology company and a spin-off of the Cleveland Clinic Foundation. Primary investors in the company include Southwest Michigan First Life Sciences Fund, Triathlon Medical Venture Partners, Hopen Therapeutics and the Michigan Economic Development Corporation. Building upon research done at the University of Kentucky and the Cleveland Clinic, Tolera Therapeutics is developing and commercializing therapies for the immune modulation market with the goal of addressing unmet medical needs with safer, more targeted solutions to reduce the risk of serious and toxic side effects often associated with immunotherapy. The company is focusing on commercializing therapeutic monoclonal antibody technology for the transplantation and autoimmune markets. Additional information concerning the company and its technology can be found on its website www.tolera.com.

Company contact:

James Herrmann
(269) 585-2100
info@tolera.com