



For immediate release

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Tolera Therapeutics granted Orphan Drug Designation for treatment of Type 1 diabetes mellitus

Kalamazoo, Michigan, Tuesday, June 22, 2010 – Tolera Therapeutics, Inc., was granted orphan drug status by the United States Food and Drug Administration (FDA) for TOL101 (anti-TCR murine monoclonal antibody, type IgM), for treatment of recent onset immune-mediated Type 1 diabetes mellitus (T1DM). Designation is granted for treatment of patients sixteen years of age and younger with immune-mediated T1DM and preserved pancreatic β -cell function, commonly referred to as juvenile diabetes.

“We are pleased with this designation,” commented John J. Puisis, President and CEO of Tolera. “Clinicians and patients need an effective and safe means to modulate the immune system, particularly for juvenile diabetes patients. Current treatments and industry pipelines offer very few solutions to advance patient care, leaving these young patients with a deteriorating disease condition. Thus far, these treatments can only offset disease symptoms, or slow disease progression, but at the cost of potentially serious side effects. We believe we are developing a therapy that will prove to be both safe and effective, thus providing the patient with a much better treatment outcome.”

The Orphan Drug Act was enacted to allow the FDA to grant a product special orphan status when it is intended to treat rare diseases or conditions -- those that affect fewer than 200,000 people annually in the United States. This special designation waives governmental filing fees, provides the drug sponsor with tax credits related to development expenses, as well as other support. In addition, orphan drug designation creates the opportunity for the sponsor to apply for orphan drug grant money from the U.S. government to help support clinical trials. As an agent with the potential to aid patients with a severe condition, TOL101 meets the stringent FDA requirements for orphan drug designation. This designation will facilitate TOL101’s entry into the clinic, where relatively few new therapies have emerged over the last ten years, and there is a growing need for safer, more targeted immunological therapeutic approaches.

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.