

## **Theratechnologies' NDA for Tesamorelin to be Reviewed by an FDA Advisory Committee**

**Montreal, Canada – November 5, 2009** – Theratechnologies (TSX:TH) today announced that the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (“FDA”) will review Theratechnologies' NDA for tesamorelin in the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. The role of the Advisory Committee, which is tentatively scheduled to meet with Theratechnologies during the first quarter of 2010, is to provide the FDA with independent opinions on the use of tesamorelin from medical experts, patient groups and various stakeholders.

“We view the solicitation of additional viewpoints from various external groups as positive and over the next few months we will work together with the FDA to prepare for the meeting,” noted Mr. Yves Rosconi, President and Chief Executive Officer of Theratechnologies.

As part of the FDA review process, the primary role of an Advisory Committee is to provide independent advice that will contribute to the quality of the agency's regulatory decision-making process. In the situation where a first-of-a-kind medical product, like tesamorelin, is evaluated for human use, it is common procedure to refer such a drug to an Advisory Committee prior to making a decision as stated in the FDA regulations. Although Advisory Committees provide their opinions to the Agency during publicly held meetings, the final decisions on marketing approvals are made by FDA.

Theratechnologies submitted an NDA to the FDA on May 29, 2009, for tesamorelin, an analogue of the growth hormone releasing factor, proposed for the treatment of excess abdominal fat in HIV patients with lipodystrophy. The FDA filed the NDA on August 12, 2009, which initiated a substantive review of the application.

### **About HIV-Associated Lipodystrophy**

Several factors including a patient's antiretroviral drug regimen and the HIV virus itself are thought to contribute to HIV-associated lipodystrophy, which is characterized by body composition changes, dyslipidemia and glucose intolerance. The changes in body composition include excess abdominal fat accumulation. There is currently no approved treatment available for the excess abdominal fat related to HIV-associated lipodystrophy, a condition that can stigmatize patients.

### **About Theratechnologies**

Theratechnologies (TSX: TH) is a Canadian biopharmaceutical company with core expertise in peptide-based therapeutics. Its most advanced compound, tesamorelin, is an analogue of the human growth hormone releasing factor.

In late 2008, Theratechnologies completed its Phase 3 clinical program which was designed to evaluate tesamorelin in treating excess abdominal fat in HIV patients with lipodystrophy. Theratechnologies signed a collaboration and licensing agreement with EMD Serono, Inc., for the commercialization of tesamorelin in the United States.

Theratechnologies' growth strategy is firmly focused on the development of tesamorelin in the United States and in other potential HIV-associated lipodystrophy markets, as well as through additional clinical programs for other medical conditions.

**Contact:**

Andrea Gilpin

Vice President, IR & Communications

Theratechnologies Inc.

Phone: 514 336-7800, ext. 205

[communications@theratech.com](mailto:communications@theratech.com)