



## **Manhattan Pharmaceuticals Granted FDA Approval to Initiate Phase I Clinical Trials for Oleoyl Estrone**

### **Phase I Trial Expected to Begin in First Quarter 2005**

New York NY, January 20, 2005 -- The United States Food and Drug Administration (FDA) has accepted an Investigational New Drug Application (IND) from Manhattan Pharmaceuticals, Inc. ("Manhattan" OTCBB: MHTT), for the human clinical testing of its orally administered obesity therapeutic, Oleoyl estrone (OE).

This IND allowance moves Manhattan forward into the next stage of OE's development and was granted on the preclinical chemistry, manufacturing, and safety data submitted to the FDA by the Company.

Manhattan expects to commence a Phase I clinical trial in Switzerland in the first quarter of 2005. The Company previously announced approval by the Swiss governmental medical regulatory authority, SwissMedic, to initiate human trials. This double-blinded, placebo controlled trial is designed to evaluate the safety and tolerability of defined doses of orally administered Oleoyl estrone in obese adults.

In November 2003, Manhattan announced the first peer reviewed publication reporting human physiologic responses to OE, including marked weight loss, during 27 months of oral administration. More recently, Company scientists reported favorable preclinical toxicology data for OE at the 13th Annual Meeting of the European Congress on Obesity in May 2004 and additional pharmacology data at the North American Association for the Study of Obesity Annual Meeting in November of 2004.

### **About Oleoyl estrone**

Oleoyl estrone is Manhattan Pharmaceuticals, Inc.'s lead product candidate. It is an orally administered small molecule shown, in extensive preclinical animal studies, to cause significant weight loss without the need for dietary modifications. In such studies, OE appears to be safe and effective with no evidence of rebound weight gain after treatment has been discontinued. OE may prove to be a safe and effective treatment for obesity, representing a significant advantage over currently available anti-obesity medications.

### **About Manhattan Pharmaceuticals, Inc.**

Manhattan Pharmaceuticals, Inc. (<http://www.manhattanpharma.com/>), a development stage pharmaceutical company, acquires and develops proprietary prescription drugs for large, underserved patient populations. In view of the worldwide obesity epidemic, the Company is developing Oleoyl estrone, an orally administered novel therapeutic for weight loss. The Company is also developing a convenient, proprietary lingual spray formulation of propofol, the world's best-selling general anesthetic, as a sedative-hypnotic for use during diagnostic and therapeutic procedures.