Manhattan Pharmaceuticals Begins Patient Dosing in First Phase I Clinical Trial for Oleoyl estrone

Trial Launches Clinical Development Program for Orally Available, Naturally Occurring Molecule to Treat Obesity

NEW YORK--(BUSINESS WIRE)--Feb. 3, 2005-- Manhattan Pharmaceuticals, Inc. ("Manhattan" OTCBB: MHTT), has begun dosing patients in its first Phase I trial in Basel, Switzerland to evaluate the safety and tolerability of defined doses of orally administered Oleoyl estrone (OE) in obese adults.

The objective of this human Phase I dose-escalation study is to determine the pharmacokinetic profile of OE, as well as its safety and tolerability in obese adult volunteers of both genders. In total, 36 obese volunteers will be randomized to receive a single dose of either OE or a placebo, in a dose-escalating manner. The Swiss medical regulatory authority, SwissMedic, issued its formal approval to initiate such a trial last month. The trial is being conducted under the Investigational New Drug Application (IND) recently accepted by the U.S. FDA and the results will be used as a part of the U.S. regulatory approval process.

"The initiation of the first Phase I study of OE brings us closer not only to demonstrating the safety and tolerability of our lead product candidate, but also to delivering a promising therapeutic to a large, underserved patient population" said Nick Rossettos, Chief Financial and Operating Officer of Manhattan Pharmaceuticals. "Based on the preclinical results to date, we believe OE has the potential to become an important treatment option for obesity."

Oleoyl estrone - Targeting the Obesity Epidemic
Orally administered formulations of OE have been demonstrated, in extensive preclinical animal studies, to cause significant weight loss and reduced caloric consumption without the need for dietary modifications. In such studies, OE appears to be safe and effective without side effects or evidence of rebound weight gain after treatment was stopped. The Company believes that OE may prove to be a safe and effective treatment for obesity, representing a significant advantage over currently available anti-obesity medications.

Manhattan believes OE could help address the obesity epidemic - one of the world's top health concerns. Nearly two-thirds of the U.S. adult population is estimated to be overweight and at least half of these are clinically obese. Though there are currently two FDA approved therapeutics on the market for the long-term treatment of obesity, market penetration remains low, possibly as a result of the modest efficacy (an average of 8-10% weight loss in the first year), and side effects reported with use of these treatment options.

Manhattan has reported favorable, peer-reviewed preclinical safety and pharmacokinetic data regarding OE at the 2004 annual meetings of the European Congress on Obesity, and the North American Association for the Study of Obesity.

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.