Manhattan Pharmaceuticals Doses First Patient Group In Phase IIA Trial For OE, Its Oral Obesity Drug Candidate

NEW YORK, NY JUNE 29 - Manhattan Pharmaceuticals, Inc. (AMEX: MHA) today announced that it commenced dosing the first group of patients in its Phase IIa clinical trial of oral Oleoyl-estrone (OE), the company's novel drug candidate for the treatment of obesity. Patient recruitment is ongoing.

The randomized, double-blind, placebo-controlled, parallel group Phase IIa study of OE is designed to evaluate the safety, preliminary efficacy, and pharmacokinetics of two 14-day cycles of escalating oral doses of the compound in obese adult subjects. Dose levels of OE will be placebo, 5, 10, and 20 mg daily. Manhattan expects that 100 subjects will be randomly enrolled into one of these four treatment groups that comprise this Phase IIa trial.

In addition to safety and tolerability, this Phase IIa study is also designed to further evaluate weight loss, maintenance of weight loss, and other therapeutic outcomes.

"This is a major step forward in the development of OE and emphasizes the excellent progress being made with the clinical program," said Alan Harris, MD, PhD, Manhattan Pharmaceuticals' chief medical officer. "Oleoyl-estrone is a promising drug candidate thought to work both centrally and peripherally."

OE is an orally administered, synthetic form of Oleoyl-estrone, a molecule that exists naturally in the body. As shown in animal studies, it is believed to work by a dual mechanism of action. Centrally, OE appears to act at the hypothalamus, resetting the body's ponderostat, the "food control center" in the brain that detects and integrates signals that control both appetite and metabolic behavior. Peripherally, OE also causes reduced storage of fat in "white fat" tissue and allows skeletal muscle to use fat as an alternate energy source.

Obesity is rapidly becoming a global epidemic. The U.S. Centers for Disease Control reports that 65 percent of Americans are overweight and 30 percent are obese. The number of clinically obese Americans is expected to grow from 73 million currently to 94 million during the next 5-6 years.

Currently marketed obesity treatments have not been shown to be particularly effective in accomplishing sustained weight loss. Even if weight loss is achieved, current obesity treatments do not reduce the likelihood of regain of lost weight once treatment has stopped. Most marketed weight loss therapeutics also cause unwanted side effects.

About Manhattan Pharmaceuticals, Inc.
Manhattan Pharmaceuticals, Inc., 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 OE, an orally administered novel therapeutic for the treatment of obesity. To meet the needs of other major, underserved medical markets while lowering development risks, Manhattan Pharmaceuticals is also developing PTH (1-34), a peptide believed to be a regulator of epidermal cell growth, for psoriasis, and Propofol Lingual Spray, 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. (http://www.manhattanpharma.com)