Manhattan Pharmaceuticals Granted FDA Approval to Initiate Phase I Clinical Trials for Propofol Lingual Spray

505(b)2 Development Pathway Leverages IV Propofol's Existing Safety Profile and Enables Accelerated Clinical Development Program

New York NY, January 27, 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 initiation of the human clinical trials required for FDA approval of Propofol Lingual Spray (Propofol LS). Propofol LS is being jointly developed with Novadel Pharma Inc. (AMEX: NVD), as a fast-acting, quick-recovery sedative for use during diagnostic and therapeutic procedures.

Manhattan continues to pursue FDA approval for Propofol LS under a 505(b)2 regulatory pathway. In July 2004, a pilot Phase I safety, tolerability, and pharmacokinetic study was completed in the United Kingdom. The results of this study support the feasibility of propofol delivery by the oral mucosal route and provided valuable data critical to the design of the clinical trials Manhattan intends to conduct under this IND.

Manhattan initiated a joint development program for Propofol LS with NovaDel Pharma, Inc. in June 2003. On April 10, 2003, Manhattan announced that it had entered into a License and Development Agreement with NovaDel Pharma Inc. for the worldwide, exclusive rights to use NovaDel's proprietary lingual spray technology to deliver propofol for preprocedural sedation.

About Propofol LS
Manhattan is developing Propofol Lingual Spray as a safe, convenient, noninvasive formulation of propofol, the world's best selling intravenous general anesthetic. The Company believes that the delivery of propofol via lingual spray will provide many advantages over currently formulated sedatives, to the benefit of patients undergoing innumerable diagnostic and therapeutic procedures each year. In particular, clinicians would have the ability to tightly control the onset, duration, and depth of sedation, with a level of reliability and accuracy previously unknown, promoting improved procedural outcomes as well as patient comfort and satisfaction. Manhattan's pilot Phase I study of Propofol LS, conducted in the United Kingdom, was a single-center, randomized, double-blind, placebo-controlled dose-escalating study of propofol lingual spray in twelve healthy adult volunteers. The study was conducted using a formulation of Propofol LS packaged in single-dose actuators designed to deliver the formulation in a fine mist to the oral mucous membranes. Propofol LS was detectable in blood as early as 4 minutes following spray administration and resulted in a mean time to maximum blood concentration of approximately 30 minutes across all doses. The mean maximum blood concentrations plateaued at the highest of the three doses tested, with mean bioavailability of the current spray formulation up to 18% of that of the intravenous formulation. No serious adverse events, nor dose-dependent changes in laboratory parameters or vital signs, occurred in any group. Physical characteristics and stability data for the formulation of Propofol LS used in this trial were previously presented by Manhattan at the 19th Annual Meeting of the Society for Ambulatory Anesthesia in Seattle in April 2004.

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.

About NovaDel Pharma Inc.
NovaDel Pharma Inc.(HTTP://WWW.NOVADEL.COM/) is a specialty pharmaceutical company engaged in the development of novel drug delivery systems for prescription and over-the-counter drugs. The Company's proprietary lingual spray technology delivery system offers the patient (i) fast onset of action; (ii) improved drug safety by reducing the required drug dosage and reducing side effects; (iii) improved patient convenience and compliance; and (iv) enhanced dosage reliability. The Company plans to develop such products independently and through collaborative arrangements with major pharmaceutical and biotech companies.