

# Manhattan Pharmaceuticals Announces License Agreement and Expanded Pipeline

NEW YORK, NY APRIL 4, 2007 - Manhattan Pharmaceuticals, Inc. (AMEX: MHA) today announced that it has acquired exclusive, North American rights to develop and commercialize two novel product candidates from Thornton & Ross Limited - the largest independent pharmaceutical manufacturer in the United Kingdom (UK). The two acquired product candidates are Altoderm™ (topical cromolyn sodium) for the treatment of atopic dermatitis and Altolyn™ (oral cromolyn sodium tablet) for the treatment of mastocytosis. The company believes the acquisition of these two product candidates is an important step in the Manhattan Pharmaceuticals corporate strategy as it allows the company to continue to create a robust pipeline while building on the existing dermatology franchise. Cromolyn sodium, also known as sodium cromoglycate, is a non-steroidal, anti-inflammatory medicine that has been used worldwide for over 35 years to treat a number of allergic conditions including asthma, allergic rhinitis (nasal allergies), allergic conjunctivitis, and mastocytosis.

Altoderm<sup>™</sup> is a novel, proprietary formulation of topical cromolyn sodium and is designed to enhance the absorption of cromolyn sodium in order to treat atopic dermatitis, or "eczema". This product candidate is currently being tested in a Phase 3 clinical trial in the UK. In a previously completed randomized, double-blind, placebo-controlled, parallel-group, Phase 3 clinical study the compound was administered for 12 weeks to 144 child subjects with moderately severe atopic dermatitis. In the study results, published in the *British Journal of Dermatology* in February 2005, Altoderm<sup>™</sup> demonstrated a statistically significant reduction in symptoms. During the study, subjects were permitted to continue with their existing treatment, in most cases this consisted of emollients and topical steroids. A positive secondary outcome of the study was a reduction in the use of topical steroids for the Altoderm<sup>™</sup>-treated subjects.

According to the National Institutes of Health (NIH), more than 15 million people in the US have symptoms of atopic dermatitis, and US health insurance companies spend more than \$1 billion per year on the condition.

Altolyn™ is a proprietary, site specific, tablet formulation of oral cromolyn sodium for the treatment of mastocytosis. This novel formulation is designed to provide optimal availability by preferentially releasing the drug in the upper part of the small intestine, the purported site of action. Early clinical experience in the UK suggests promising activity in patients with various allergic disorders, including inflammatory bowel conditions. Oral cromolyn sodium is the active ingredient in Gastrocrom(R) an oral liquid solution that is currently FDA approved for the treatment of mastocytosis.

"Altoderm<sup>TM</sup> and Altolyn<sup>TM</sup> are innovative topical and oral formulations of cromolyn sodium, a widely used molecule with a well established safety profile. We believe Altoderm<sup>TM</sup> has the potential to provide an important treatment alternative to steroids and immunomodulators for patients with atopic dermatitis," stated Doug Abel, President and Chief Executive Officer. "Our new relationship with Thornton & Ross Limited represents an ideal strategic opportunity for Manhattan Pharmaceuticals. Thortnon & Ross is an industry leader for prescription and consumer products in the UK, with a pipeline of innovative healthcare products. The addition of these two product candidates is an important step in our corporate strategy as it allows us to grow our existing dermatology business, while continuing to build a strong, diverse pipeline."

This licensing transaction increases the Manhattan Pharmaceuticals pipeline to five clinical stage product candidates.

## **About Atopic Dermatitis**

According to the NIH, more than 15 million people in the U.S. have symptoms of atopic dermatitis with an estimated 20 percent of those being infants and young children. Roughly 60 percent of these infants continue to have one or more symptoms in adulthood. It affects both males and females and accounts for 10 to 20 percent of all visits to dermatologists. Atopic dermatitis is a chronic (long-lasting) disease that affects the skin. It is not contagious; it cannot be passed from one person to another. In atopic dermatitis, the skin becomes extremely itchy. Scratching leads to redness, swelling, cracking, "weeping" clear fluid, and finally, crusting and scaling. The cause of atopic dermatitis is not known, but the disease seems to result from a combination of genetic (hereditary) and environmental factors. The most common symptoms are dry, itchy skin and rashes on the face, inside the elbows and behind the knees, and on the hands and feet.

Currently, topical corticosteroids are the primary anti-inflammatory treatment for atopic dermatitis. They are extremely effective in controlling acute exacerbations, and are also used for long-term maintenance treatment when emollients alone do not provide adequate control. However, local side effects are common, in particular skin thinning, telangiectasis, bruising, hypopigmentation, acne, striae and secondary infection. There is, therefore, an understandable reluctance on the part of patients, parents and physicians to use topical corticosteroids on a long-term basis. Recently, topical formulations of the immunosuppressive drugs tacrolimus and pimecrolimus have been introduced as anti-inflammatory agents. However, there is limited evidence of their long-term safety.

### **About Mastocytosis**

Mastocytosis is a rare disorder that occurs in both children and adults. It is caused by the presence of too many mast cells in the body. Mast cells are found in skin, linings of the stomach and intestine, and connective tissue (such as cartilage and tendons). Mast cells play an important role in helping the immune systems defend these tissues from disease. They release chemical "alarms" such as histamine and cytokines to attract other key players of the immune defense system to sites in the body where they might be needed. People with mastocytosis experience abdominal discomfort, nausea and vomiting, ulcers, diarrhea, and skin lesions.

## 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 both common obesity and morbid obesity. To meet the needs of other major, underserved medical markets Manhattan Pharmaceuticals is also developing topical PTH (1-34), a peptide believed to be a regulator of epidermal cell growth, for the treatment of 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)

#### About Thornton & Ross Limited<

Founded in Huddersfield, Thornton & Ross (T&R) is a privately-owned company which has grown to become a significant player within the UK healthcare market with brands which span the Rx, OTC and consumer sectors. Its leading brands include COVONIA (cough cold and flu range), HEDRIN (Headlice treatment), CARE (range of everyday medicines), ALGESAL and TRANSVASIN (topical analgesics), SETLERS and GASTROCOTE (heartburn and indigestion remedies). T&R's leading household brand is ZOFLORA a range of floral disinfectants.

T&R manufactures the majority of its products, specializing in pharmaceutical liquids and creams. The company employs 350 people and has a turnover approaching £40 million. (www.thorntonross.com)

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