

## MANHATTAN PHARMACEUTICALS' TOPICAL PSORIASIS TREATMENT IN PHASE IIA TRIAL

NEW YORK, NY DEC 28 - Manhattan Pharmaceuticals, Inc. (AMEX: MHA) reported that a Phase IIA study has been initiated with PTH (1-34), its experimental product for the topical treatment of psoriasis. The investigator-initiated study is being conducted at Boston University Medical Center.

The double-blinded, placebo-controlled trial will treat 40 adult volunteers up to age 80 with daily application of a placebo and two strengths of PTH (1-34), all delivered in the proprietary Novasome? base developed by IGI, Inc. (AMEX: IG).

The aim of the study is to determine the therapeutic efficacy and safety of PTH (1-34) (a parathyroid hormone-related peptide analog) for the treatment of adult patients with psoriatic lesions.

Topical PTH (1-34) is based on a naturally occurring protein in skin and hair follicles that serves to regulate the growth of skin cells. When applied to psoriatic lesions in an earlier Phase I/II clinical trial, PTH (1-34) restored the normal development and migration of skin cells, preventing cell build-up and the formation of plaques.

Because PTH (1-34) is the active ingredient in a currently approved injectable product for osteoporosis, Manhattan Pharmaceuticals expects to be able to seek approval of its topical form of the drug under the provisions of a 505(b)(2) regulatory submission, a form of New Drug Application (NDA) that relies on the FDA's previous findings in approved NDAs and published literature. This limits new systemic safety data requirements. Psoriasis affects nearly 4.5 million Americans today, with 15-25 percent of those patients developing a moderate to severe form of the disease. Psoriasis patients in the US seeking treatment account for nearly 2.4 million dermatology visits a year, at a total cost of \$3 billion.

Current topical treatments for psoriasis range from traditional tar salve, which has limited efficacy, to tazarotene gel, which commonly causes localized itching and burning. Topical corticosteroids are a mainstay in the treatment of localized psoriasis; however, they are not recommended for long-term use and can have significant side effects and intolerability issues.

The most widely prescribed non-steroidal compound is a topical form of calcipotriene (brand name Dovonex ), which has been owned and promoted by a variety of companies since its introduction in 1994 and currently generates about \$140 million in US product sales and significant additional revenue worldwide. PTH (1-34)'s early data shows a potentially stronger product profile than Dovonex .

### What Is Psoriasis?

Psoriasis is a common, chronic, immune-mediated skin disease of unknown cause that results in the overproduction and abnormally rapid migration of skin cells to the skin's surface. The skin is unable to shed these cells quickly enough, and the cells then accumulate in dry, thick patches called plaques. Plaques may appear anywhere in the body and can irritate the skin, causing mild to severe discomfort or disability.

### About Manhattan Pharmaceuticals, Inc.

Manhattan Pharmaceuticals, Inc. ([www.manhattanpharma.com](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 OE, an orally administered novel therapeutic for weight loss. To meet the needs of other major, underserved medical markets while lowering development risks, Manhattan Pharmaceuticals 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.

### About IGI, Inc.

IGI, Inc. is a company committed to growth by applying proprietary technologies to achieve cost-effective solutions for varied customer needs. IGI offers the patented Novasome? lipid vesicle encapsulation technology which contributes value-added qualities to cosmetics, skin care products, dermatological formulations and other consumer products, providing improved dermal absorption, low potential for irritations, controlled and sustained release as well as improved stability. IGI has licensed Novasome? lipid vesicle encapsulation technology to leading global dermatological and skin care companies including Johnson & Johnson Consumer Products, Inc., Est?e Lauder Companies, Chatterm Inc., Genesis Pharmaceutical, Inc. and Apollo Pharmaceutical, Inc., and recently sub-licensed the rights to obtain FDA approval for and market IGI's PTH (1-34) compound using Novasome? lipid vesicle encapsulation technology for psoriasis, which is slated for Phase II clinical trials, to Tarpan

Therapeutics, Inc., which was acquired by Manhattan Pharmaceuticals in April 2005. IGI is also exploring the licensing of the topical PTH (7-34) compound for the prevention/treatment of chemotherapy induced alopecia in patients undergoing chemotherapy.