

## **Pro-Pharmaceuticals Plans to Submit a New Drug Application for DAVANAT<sup>®</sup>, as a Functional Excipient, with 5-FU to Treat Cancer**

**Newton, Mass. (April 12, 2007) Pro-Pharmaceuticals, Inc. (Amex: PRW)**, a developer of novel first-in-class carbohydrate compounds, received comments from the U.S. Food & Drug Administration (FDA) relative to its plans for submitting a New Drug Application (NDA), under Section 505 (b)(2) for DAVANAT<sup>®</sup>, as a functional excipient, to be co-administered with 5-Fluorouracil (5-FU) to treat cancer patients.

“In March, we sent the FDA substantial information on chemistry and completed pre-clinical and clinical data, along with a list of questions to submit an NDA to allow DAVANAT<sup>®</sup>, to be used as a functional excipient, intravenously with 5-FU, for cancer applications for a filing under Section 505 (b)(2),” said David Platt, Ph.D., President & Chief Executive Officer, Pro-Pharmaceuticals, Inc.

“The letter response from the FDA was in line with our expectation. The FDA’s response provides us with a clear roadmap in terms of what additional information, primarily manufacturing, they need to allow our NDA submission. No additional toxicology or clinical tests or trials are required. We plan to file an NDA submission as soon as we complete the additional manufacturing information needed.”

### **DAVANAT<sup>®</sup> as a Functional Excipient**

Excipients are the materials other than the active pharmaceutical ingredients incorporated into dosage forms to play specific functional roles, including modulating solubility, increasing stability and bioavailability, and play critical roles in the effectiveness, safety, potency, purity and stability of a product. In complex products such as chemotherapeutics, the functional role of an excipient is also important when used as a drug delivery system to reduce toxicity and/or increase efficacy.

The Company is using Section 505 (b)(2) to obtain more timely and efficient marketing approval of new formulations of previously approved therapeutics which incorporate the Company’s proprietary drug target delivery compound. The Company is seeking approval for co-administration of DAVANAT<sup>®</sup> (a galactomannan) with FDA-approved 5-FU for intravenous injection for the treatment of cancer. 5-FU is one of the most widely used chemotherapy drugs in the world and is used to treat various types of cancers, including colorectal, breast and gastrointestinal.

### **About Section 505 (b)(2)**

Section 505 (b)(2) allows the FDA to approve a drug on the basis of data in the scientific literature or data previously cited by the FDA as the basis for the approval of related drugs. This procedure makes it potentially faster for drug developers to obtain approval of new formulations of drugs based, in part, on proprietary data of the developer of the original drug. Section 505 (b)(2) of the U.S. Food, Drug & Cosmetic Act permits the FDA to approve a NDA in part on the basis of published literature or on a previous finding of safety or effectiveness of a drug. A 505 (b)(2) application can apply to new chemical entities or to changes to previously approved drugs. Galactomannan are approved for formulation and deliveries, such as oral, topical and vaginal delivery of drugs. DAVANAT<sup>®</sup> extends the use of galactomannan to the delivery of chemotherapeutic drugs. In this application, DAVANAT<sup>®</sup> is co-administered with 5-FU for intravenous delivery.

The Company is also continuing its clinical development plan for DAVANAT<sup>®</sup> in combination with 5-FU and other chemotherapy and biological drugs, such as leucovorin and AVASTIN<sup>®</sup>. The Company plans to initiate a Phase III trial after reporting interim results from the ongoing Phase II trials. The FDA provided comments on the design of the Company’s Phase III trial for colorectal cancer.

### **About DAVANAT<sup>®</sup>**

DAVANAT<sup>®</sup>, the Company’s lead product candidate, is a polysaccharide, carbohydrate polymer, composed of mannose and galactose (galactomannan). The Company believes DAVANAT<sup>®</sup>’s mechanism of action is based upon binding to lectins on the surface of cancer cells. Lectins are carbohydrate-binding proteins found on cell surfaces. It is theorized that DAVANAT<sup>®</sup> targets

specific lectin receptors (Galectins) that are over-expressed on cancer cells. Current research indicates that Galectins affect cell development and play important roles in cancer, including tumor cell survival, angiogenesis and tumor metastasis. This form of targeted delivery may allow for higher doses of chemotherapy administration with no increase in toxicity.

### **Pro-Pharmaceuticals, Inc. – Advancing Drugs Through Glycoscience®**

Pro-Pharmaceuticals is a development stage pharmaceutical company engaged in the discovery, development and commercialization of first-in-class carbohydrate-based therapeutic compounds for advanced treatment of cancer, liver, microbial, cardiovascular and inflammatory diseases. The Company's initial focus is the development and commercialization of a new generation of anti-cancer treatments using carbohydrate polymers with the intent of enhancing the safety and efficacy of standard cancer agents. The Company's technology capitalizes on the natural property of carbohydrates to increase the efficacy and reduce the toxicity of chemotherapeutics; "rescue" drugs that were shelved for toxicity or "half-life" issues; increase the solubility of existing drugs, and develop carbohydrate polymers as new chemical entities.

The Company has been conducting clinical and pre-clinical studies with its lead compound, DAVANAT®, in combination with 5-FU, leucovorin, irinotecan, doxorubicin, oxaliplatin, paclitaxel, cisplatin, and bevacizumab (Avastin®). Results show that DAVANAT® exhibits a broad spectrum of activity with tested drugs. The Company is developing additional carbohydrate-based therapeutic compounds that are currently in the pre-clinical stage of development. Founded in 2000, the Company is headquartered in Newton, Mass. Additional information is available at [www.pro-pharmaceuticals.com](http://www.pro-pharmaceuticals.com).

**FORWARD LOOKING STATEMENTS:** Any statements in this news release about future expectations, plans and prospects for the Company, including without limitation statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements as defined in the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management's current expectations and are subject to a number of factors and uncertainties, which could cause actual results to differ materially from those described in such statements. We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, the following: uncertainties as to the utility and market for our potential products; uncertainties associated with pre-clinical and clinical trials of our product candidates; our limited experience in product development and expected dependence on potential licensees and collaborators for commercial manufacturing, sales, distribution and marketing of our potential products; possible development by competitors of competing products and technologies; lack of assurance regarding patent and other protection of our proprietary technology; compliance with and change of government regulation of our activities, facilities and personnel; uncertainties as to the extent of reimbursement for our potential products by government and private health insurers; our dependence on key personnel; our history of operating losses and accumulated deficit; and economic conditions related to the biotechnology and bio-pharmaceutical industry. We cannot assure you that we have identified all the factors that create uncertainties. Readers should not place undue reliance on forward-looking statements.

More information about those risks and uncertainties is contained and discussed in the "Management Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" sections of the Company's most recent quarterly or annual report and in the Company's other reports filed with the Securities and Exchange Commission. The forward-looking statements represent the Company's views as of the date of this news release and should not be relied upon to represent the Company's views as of a subsequent date. While the Company anticipates that subsequent events may cause the Company's views to change, the Company disclaims any obligation to update such forward-looking statements.

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