

## **PRO-PHARMACEUTICALS RECEIVES POSITIVE FDA FEEDBACK ON DAVANAT® PHASE III CLINICAL TRIAL DESIGN TO TREAT PATIENTS WITH COLORECTAL CANCER**

Newton, Mass. (January 10, 2011) Pro-Pharmaceuticals, Inc. (OTC: PRWP), the leading developer of therapeutics that target Galectin receptors to treat cancer and fibrosis, today announced that on December 17, 2010, Company representatives met with officials from the U.S. Food & Drug Administration (FDA) to present its Phase III clinical development program for DAVANAT®. Agreement was reached on the design of a pivotal, randomized, controlled, and blinded Phase III clinical trial of DAVANAT® co-administered with standard chemotherapy for second line treatment of patients with metastatic colorectal cancer. The primary end point for the trial will be increased survival with a secondary end point of reduced serious side effects of chemotherapy.

"This successful meeting with the FDA clears the way for Pro-Pharmaceuticals to begin the Phase III development program following submission and approval of the final protocol," said Peter G. Traber, M.D., Chief Medical Officer, Pro-Pharmaceuticals. "Extending patient survival, while decreasing severe adverse effects of chemotherapy, is significant and unique. The successful meeting with the FDA is an essential step in the DAVANAT® development program and we look forward to implementing it in 2011."

"The Phase III development program is an important milestone towards achieving our goal of commercializing DAVANAT®, an innovative approach to treating cancer patients," said Theodore Zucconi, Ph.D., Chief Executive Officer, Pro-Pharmaceuticals. "We are highly encouraged by the findings of our previous clinical studies, which suggest that DAVANAT® may be an effective anti-cancer agent that also reduces side effects. We are optimistic that our novel Galectin-targeting compound may improve treatment for metastatic colorectal cancer.

"The positive feedback from the FDA meeting validates our strategy for approval in the U.S. This adds to our overall approach to commercialization of DAVANAT® which includes expected approval in Colombia, South America in 2011, and the expanded application of DAVANAT® in cancer vaccine, being developed in collaboration with the Ludwig Institute in Brussels. Blocking Galectins is a significant new tool in the fight against cancer," Zucconi said.

Results to date show that the Company's Galectin-targeting compounds also have reversed liver fibrosis in animal models, demonstrating that Galectins are involved in multiple diseases. The ability to block Galectins is a potential therapy even for diseases that have no present effective therapy, such as fibrosis/cirrhosis of the liver. The Company is developing its GM and GR Series of compounds for treating liver fibrosis/cirrhosis by collaborating with Dr. Scott Friedman at the Mount Sinai School of Medicine, a world leader in liver research.

### About DAVANAT®

DAVANAT®, the Company's lead product candidate, is a polysaccharide polymer that targets Galectin receptors on cancer cells and interferes with their activity. Peer-reviewed studies have demonstrated that Galectins affect cell development and play important roles in cancer, including tumor cell survival, angiogenesis, tumor metastasis and give the tumor the ability to evade

the immune system. To date, DAVANAT® has been administered to approximately 100 cancer patients. Data from a Phase II trial for end-stage colorectal cancer patients showed that DAVANAT® in combination with 5-FU extended median survival by 46% compared with the best standard of care as determined by the patients' physicians. Clinical trial results also showed that patients experienced fewer serious adverse side effects of chemotherapy which has the potential to reduce hospitalizations and improve quality of life.

#### About GM and GR Series of Fibrosis Compounds

The GM and GR series of compounds are first-in-class, novel carbohydrate compounds that significantly reduced collagen expression and reversed fibrosis in animal models. Uncontrolled collagen expression is a pathological process that occurs during the fibrotic process, affecting various organs leading to scar tissue. Chemical toxicity, microbial infection or physical injury cause hepatic, renal and other types of fibrosis. Carbohydrate polymers were synthesized and screened to inhibit collagen production in in-vivo and in-vitro fibrosis models.

#### About Pro-Pharmaceuticals, Inc.

Pro-Pharmaceuticals, OTC: PRWP, the leader in the field of Galectin therapeutics, is engaged in the discovery, development and commercialization of therapeutics that target Galectin receptors for advanced treatment of cancer and fibrosis. Initially, the product pipeline is focused on increasing the efficacy and decreasing the toxicity of chemotherapy drugs. 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 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 and not place undue reliance on forward-looking statements.

More information about those risks and uncertainties is contained and discussed in 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.

DAVANAT is a registered trademark of Pro-Pharmaceuticals.

Contact: Pro-Pharmaceuticals, Inc., Anthony D. Squeglia: 617.559.0033; [squeglia@pro-pharmaceuticals.com](mailto:squeglia@pro-pharmaceuticals.com).