



**Watson Announces Positive Data for RAPAFLO™(silodosin), Its Investigational Product for BPH, at Regional AUA Conferences**

*-- Results demonstrate the efficacy, safety and tolerability of RAPAFLO™ alone or in combination with treatments for erectile dysfunction --*

**Corona, Calif., Sept. 29, 2008** – Watson Pharmaceuticals, Inc. (NYSE: WPI), a leading specialty pharmaceutical company, announced today that investigators presented efficacy and safety data on silodosin, its investigational treatment for benign prostatic hyperplasia (BPH, or prostate enlargement), at two regional meetings of the American Urological Association (AUA). The trade name for silodosin will be RAPAFLO™.

These abstracts included results of Phase 3 studies, which showed that treatment with RAPAFLO for up to one year effectively reduces the symptoms of BPH and is well tolerated without causing any significant changes in blood pressure or adverse cardiac effects. Cardiac safety data further demonstrated that RAPAFLO, used alone or in combination with medications for erectile dysfunction (ED), showed only minimal effects on blood pressure or heart rate.

“We are excited by these clinical data as they further support the strong and sustained efficacy, as well as the safety and tolerability of RAPAFLO that have been demonstrated in other trials,” said Edward Heimers, Jr., Executive Vice President and President of Watson’s Brand Division. “As a highly selective alpha-1A blocker, we believe that RAPAFLO will address an important medical need in urology. Earlier this year, the New Drug Application for RAPAFLO was filed, and we look forward to working with the U.S., Food and Drug Administration to make this treatment option available to patients.”

*Data at the New England Regional AUA*

At this year’s New England Regional meeting of the AUA, investigators presented two abstracts on the efficacy and safety of RAPAFLO.

The first abstract was a pooled analysis of two Phase 3 double-blind, placebo-controlled trials involving 923 generally healthy men ages 50 or older, with signs and symptoms of BPH, including a peak urine flow rate (Qmax) between 4 and 15 mL/sec (mean of 8.7 to 8.9) and International Prostate Symptom Score (IPSS)  $\geq 13$  (mean of 21.3). Patients were randomized to either 8 mg RAPAFLO once daily (n=466) or placebo (n=457) for 12 weeks.

After 12 weeks of treatment, RAPAFLO significantly improved urinary symptoms, including IPSS (the primary endpoint), compared to placebo (mean reduction of -6.4 vs. -3.5, respectively;  $p < 0.0001$ ). On secondary measures, RAPAFLO improved Qmax scores both at 2 to 6 hours following the first dose (mean improvement of 2.8 mL/sec vs. 1.5 mL/sec for placebo;  $p < 0.0001$ ) and after 12 weeks (mean improvement of 2.6 vs. 1.5 for placebo;  $p = 0.0007$ ). In addition to reducing overall IPSS, RAPAFLO also improved IPSS subscores at 12 weeks, including irritative subscore (mean decline of -2.3 vs. -1.4 for placebo;  $p < 0.0001$ ), and obstructive subscore (mean decline of -4.0 vs. -2.1 for placebo;  $p < 0.0001$ ).

Over the course of 12 weeks, treatment was well tolerated and the effect on blood pressure was similar between the RAPAFLO and placebo groups. Incidences of treatment-related dizziness and headache were low. Adverse events were minimal and were generally mild and related to retrograde ejaculation (reduced semen). There were no treatment-related cardiac events or hypertension.

The second abstract included data from a 9-month, open-label extension trial involving patients who had successfully completed the two previous 12-week, Phase 3 trials. A total of 661 patients were enrolled to receive RAPAFLO 8 mg once daily for an additional 40 weeks; 435 (65.8%) completed the extension study. A safety evaluation was based on adverse events, vital signs and clinical laboratory tests, electrocardiography (ECG), and physical examinations. An efficacy endpoint was change in IPSS at 40 weeks.

All 661 patients were included in the safety evaluation. Over the course of one-year of treatment, RAPAFLO was shown to be safe and well tolerated. Sixty-five percent (65.2%) of all patients reported at least one adverse event; less than one third of these

(28.4%) were drug related. There were no serious drug-related adverse events. RAPAFLO was not associated with any clinically meaningful changes in blood pressure, clinical laboratory parameters, ECG results, or physical examination findings. Retrograde ejaculation (reduced semen) was the most common adverse event, though it rarely leads to drug discontinuation.

In the evaluable population of 429 (64.9%) patients, the IPSS decreased by a mean of 3.1 points between weeks 0 and 40. Although the change was larger (mean -4.4 points) in patients previously given placebo, the total score also decreased (mean -1.6 points) in patients previously treated with RAPAFLO. Treatment with RAPAFLO for up to one year also reduced IPSS irritative subscore (-1.7 points in patients previously on placebo and -0.6 in patients continuing RAPAFLO) and obstructive subscore (-2.7 in patients previously on placebo and -1.0 in patients continuing RAPAFLO).

#### *Data at the Mid Atlantic Regional AUA*

A placebo-controlled, open-label, crossover trial, presented at the Mid Atlantic Regional meeting, evaluated the concomitant use of RAPAFLO with the maximum doses of sildenafil or tadalafil, two agents commonly used to treat ED.

In the study, 22 healthy men (ages 45 to 78 years) received 8 mg RAPAFLO once daily for 21 days. On days 7, 14, and 21, subjects randomly received a single dose of 100 mg sildenafil, 20 mg tadalafil, or placebo. Resting (baseline) and standing orthostatic measurements were performed 0h (predose) to 12h after single-dose treatment. A positive orthostatic test was defined as a decrease in systolic (or diastolic) blood pressure by >30 (or >20) mm Hg, increased heart rate (>20 bpm), or orthostatic symptoms on change of position, such as dizziness.

Overall, concomitant use of RAPAFLO and maximum doses of sildenafil or tadalafil in healthy men caused no symptomatic changes in blood pressure, heart rate, or orthostatic symptoms. The cumulative number of positive orthostatic tests was similar for all treatments – in 16 subjects <65 years (sildenafil, 28; tadalafil, 27; placebo 29) and in six subjects ≥65 years (sildenafil, 6; tadalafil, 8; placebo 5).

“These data provide important new evidence about this potential treatment option for BPH. Considering that many men with BPH also have other co-morbid conditions, including erectile dysfunction, heart failure, hypertension and coronary artery disease, it’s important to find complementary treatments that can be used with other medications without deleterious cardiovascular interactions, including the prolongation of the QTc interval and do not complicate patient care,” said Norman Lepor, M.D., a cardiologist and associate clinical professor of medicine, University of California, Los Angeles (UCLA) and attending cardiologist at the Heart Institute at Cedars-Sinai Medical Center.

### **About RAPAFLO™ (silodosin)**

RAPAFLO is a highly selective alpha-1 adrenergic receptor antagonist under development in the US for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). RAPAFLO binds with high affinity to the alpha (1A) receptors in the prostate causing the smooth muscles in these tissues to relax, resulting in an improvement in urine flow and a reduction in BPH symptoms. The binding affinity for the alpha (1B) receptors that cause smooth muscle relaxation and blood pressure effects in the cardiovascular system is significantly lower, thereby maximizing target organ activity for treating BPH while minimizing the potential for blood pressure effects. RAPAFLO was originally developed by Kissei Pharmaceutical Co., Ltd. in Japan and licensed to Watson for the US, Canada and Mexico markets.

### **About Watson Pharmaceuticals, Inc.**

Watson Pharmaceuticals, Inc., headquartered in Corona, CA, is a leading specialty pharmaceutical company that develops, manufactures, markets, sells and distributes brand and generic pharmaceutical products. Watson pursues a growth strategy combining internal product development, strategic alliances and collaborations and synergistic acquisitions of products and businesses.

The mission of Watson Urology is to offer products and services that improve the quality of patients' lives, and satisfy the needs of physicians who specialize in the diagnosis, management, and treatment of urological disorders. By advancing education and support for urological diseases, we are creating the differences that make life more livable.

In the U.S., the Watson portfolio includes: Oxytrol<sup>®</sup>; TRELSTAR<sup>®</sup> LA; TRELSTAR<sup>®</sup> Depot; Androderm<sup>®</sup>; ProQuin<sup>®</sup> XR, under a co-promotion agreement with Depomed, Inc.; and AndroGel<sup>®</sup>, under a co-promotion agreement with Solvay Pharmaceuticals, Inc. The Watson portfolio also includes a number of products under development including: silodosin, a product under development for the treatment of benign prostatic hyperplasia; a six-month formulation of TRELSTAR<sup>®</sup> (triptorelin pamoate for injectable suspension), under development for the treatment of advanced prostate cancer; and OTG, under development for overactive bladder.

For press releases and other company information, visit Watson Pharmaceuticals' Web site at <http://www.watson.com>.

### **Forward-Looking Statement**

Any statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Watson's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Watson disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Watson's current expectations depending upon a number of factors affecting Watson's business. These factors include, among others, the difficulty of predicting the timing or outcome of product development efforts and FDA or other regulatory agency approvals or actions, if any; whether the results of clinical trials for silodosin and other information will be sufficient to support approval by FDA or other regulatory authorities; the impact of competitive products and pricing; market acceptance of and continued demand for Watson's products, including silodosin; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Watson's periodic public filings with the Securities and Exchange Commission, including but not limited to Watson's Annual Report on Form 10-K for the year ended December 31, 2007.

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