

Petros Pharmaceuticals Executes Successful Initial Test for App Comprehension as Part of FDA Pathway for Over-the-Counter Access for STENDRA(R) (avanafil)

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Company is currently conducting larger scale comprehension test to confirm results in compliance with FDA discussions

NEW YORK, NY / ACCESSWIRE / September 11, 2024 / Petros Pharmaceuticals, Inc. (NASDAQ:PTPI) ("Petros" or the "Company"), a company focused on expanding consumer access to medication through over-the-counter ("OTC") drug development programs, today announced results of an initial study to determine consumer comprehension of the messaging in its App Technology ("App Comp"), which has unique differences from the current Drug Facts Label ("DFL"). Of the 31 objectives, 29 scored >90% comprehension Point Estimate ("PE"), 30 scored >86.7% comprehension PE, and all scored \geq 80% comprehension PE. 21 scored 100% comprehension PE. The results of the study demonstrated that the vast majority of communications were well understood by the patients in the study.

The App Comp study evaluated consumer understanding of 31 distinct messages that appeared either on a desktop or a mobile device. The expected threshold of understanding was 90%, of which only two were evaluated lower, as scored by PE.

The results of this study, while supportive as a standalone study of the functionality of the App Technology, were designed to provide guidance to the Company in connection with the development of a larger-scale App Comp with a larger patient population, estimated to include about 400 patients. The Company expects to receive results from the larger study, which is currently underway, by Q4 2024.

Fady Boctor, Petros' President and Chief Commercial Officer, commented, "We continue to work closely with the FDA to help ensure that we are aligned with their objectives as we continue to work toward the expanded access of STENDRA through OTC distribution. This initial App Comp study, which was executed in two parts, shows tremendous progress in the development of the App Technology, which will be the cornerstone of our screening process to provide OTC access. We are encouraged by the comprehension we've seen in these messages across the board, relative to the Drug Facts Label, and continue to refine based on the limited number of questions that still score below 90%. We look forward to sharing the results of the larger study in the near future."

About Petros Pharmaceuticals

Petros Pharmaceuticals, Inc. is committed to the goal of becoming a leading innovator in the emerging self-care market driving expanded access to key prescription pharmaceuticals as OTC treatment options. Currently, Petros is pursuing increased access for its flagship prescription ED therapy, STENDRA® (avanafil), via potential OTC designation (see important safety information below.) If ultimately approved by the FDA for OTC access, STENDRA® (avanafil) may be the first in its class to achieve this marketing status, also establishing company know how as a potentially proven platform for other prospective prescription therapeutics.

About the OTC Pathway

The process of switching a prescription medication to OTC first involves the design of a Drug Facts Label ("DFL") that is well understood by potential consumers. Then, data must show that consumers can make an appropriate informed decision to use or not to use the product based only upon the information on the DFL and their personal medical history. Then consumers must demonstrate that they can properly use the product based upon the information on the DFL. To accomplish this, the FDA ordinarily requires a consumer tested OTC DFL. Such testing includes conduct of iterative Label Comprehension Studies (LCS) in the general population, Self-Selection Studies (SSS) in a population interested in using the product and in specific populations who may be harmed if they use the product, and usually one Actual Use Trial (AUT) demonstrating safe and appropriate use by consumers in a simulated OTC setting.

The regulations that FDA is currently finalizing introduced Additional Conditions for Nonprescription Use ("ACNU") criteria that enable correct self-selection by consumers and may expand OTC access to medications that formerly could only be available by prescription. An ACNU may be an innovative computerized tool, or the additional conditions may use other approaches that support the switch process.

Important Safety Information about STENDRA® (avanafil)

STENDRA® (avanafil), originally launched by Auxilium Pharmaceuticals prior to its sale to Endo Pharmaceuticals, is an oral phosphodiesterase 5 (PDE5) inhibitor for the treatment of erectile dysfunction. STENDRA® (avanafil) is not for use in women or children. It is not known if STENDRA® (avanafil) is safe and effective in women or children

under 18 years of age. A 100-mg and 200-mg tablet can be taken as early as ~15 minutes before sexual activity. STENDRA® (avanafil) only works with sexual stimulation and should not be taken more than once a day. STENDRA can be taken with or without food; do not drink too much alcohol when taking STENDRA® (avanafil) (for example, more than three glasses of wine or three shots of whiskey) as it can increase chances of side effects. Of people enrolled in clinical trials, 1.4%, 2.0%, and 2.0%, respectively, stopped taking STENDRA® (avanafil) (50 mg, 100 mg, or 200 mg) due to side effects compared to 1.7% taking a placebo. STENDRA® (avanafil) was designed and developed expressly for erectile dysfunction.

STENDRA is contraindicated for any form of organic nitrates, in patients with known hypersensitivity to any component of the tablet, and in patients who are using a guanylate cyclase stimulator.

Patients should not use STENDRA if sexual activity is inadvisable due to cardiovascular status or any other reason. Before taking STENDRA, tell your doctor if you have had any kind of heart issues including heart attack, heart failure, angina and irregular heartbeat or have elevated or low blood pressure.

Use of STENDRA with alpha-blockers, other antihypertensives, or substantial amounts of alcohol (greater than three units) may lead to hypotension.

Patients should seek emergency treatment if an erection lasts greater than 4 hours.

Patients should stop STENDRA and seek medical care if a sudden loss of vision occurs in one or both eyes, which could be a sign of Non-Arteritic Ischemic Optic Neuropathy ("NAION"). Doctors should discuss with patients the increased risk of NAION in patients with a history of NAION.

Patients should stop taking STENDRA and seek prompt medical attention in the event of sudden decrease or loss of hearing.

STENDRA can potentiate the hypotensive effect of nitrates, alpha blockers, antihypertensives, and alcohol.

CYP3A4 inhibitors (e.g., ketoconazole, ritonavir, erythromycin) increase STENDRA exposure. For patients taking concomitant strong CYP3A4 inhibitors (including ketoconazole, ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir and telithromycin), do not use STENDRA.

Combination with Other PDE5 Inhibitors or Erectile Dysfunction Therapies is not recommended.

The safety of STENDRA is unknown in patients with bleeding disorders and patients with active peptic ulceration.

The use of STENDRA offers no protection against sexually transmitted diseases including HIV. Consider counseling

patients on protective measures for sexually transmitted diseases.

The most common adverse reactions reported with use of STENDRA include headache, flushing, nasal congestion, nasopharyngitis, and back pain.

For more information about STENDRA, call 844-458-4887. If you would like to report an adverse event or product complaint, please contact us at 844-458-4887.

You are encouraged to report negative side effects of prescription drugs to the FDA by calling 1-800-FDA-1088, or at www.fda.gov/medwatch.

Please see the full **Prescribing Information** and **Patient Information**.

Cautionary Note Regarding Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based upon Petros Pharmaceuticals, Inc.'s ("Petros," "we," "our," "us" or the "Company") management's assumptions, expectations, projections, intentions, and beliefs about future events. In some cases, predictive, future-tense or forward-looking words such as "intend," "develop," "goal," "plan," "predict," "may," "will," "project," "estimate," "anticipate," "believe," "expect," "continue," "potential," "opportunity," "forecast," "should," "target," "strategy" and similar expressions, whether in the negative or affirmative, that reflect our current views with respect to future events and operational, economic and financial performance are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. Such forward-looking statements are only predictions, and actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of risks and uncertainties, Petros' ability to execute on its business strategy, including its plans to develop and commercialize its product candidates; Petros' ability to comply with obligations as a public reporting company; Petros' ability to maintain compliance with the Nasdaq Stock Market's listing standards; risks related to Petros' ability to continue as a going concern; risks related to Petros' history of incurring significant losses; risks related to Petros' dependence on the commercialization of a single product, STENDRA®; and risks related to Petros' ability to obtain regulatory approvals for, or market acceptance of, any of its products or product candidates. Additional factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements are contained in the Company's periodic reports and in other filings that the Company has filed, or may file, with the U.S. Securities and Exchange Commission (the "SEC") under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere. The Company cautions readers that the forward-looking statements included in this press release represent our beliefs, expectations, estimates and assumptions

only as of the date of hereof and are not intended to give any assurance as to future results. New factors emerge from time to time, and it is not possible for us to predict all these factors. Further, the Company cannot assess the effect of each such factor on our business or the extent to which any factor, or combination of factors, may cause actual results to be materially different from those contained in any forward-looking statement. Accordingly, you should not unduly rely on any forward-looking statements.

The Company undertakes no obligation to update or revise any forward-looking statements contained in this press release, whether as a result of new information, future events, a change in our views or expectations or otherwise, except as required by federal securities laws.

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