PLx Pharma Inc. Provides Regulatory Update on VAZALORE

January 6, 2020

-- PLx Aligning with the FDA on Data Requirements for VAZALORE
-- FDA Approves Labeling for 325 mg --
-- Expect to Launch VAZALORE in late 2020 --

SPARTA, N.J., Jan. 06, 2020 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP) ("PLx" or the "Company"), a late-stage specialty pharmaceutical company initially focused on developing its clinically validated and patent-protected PLxGuard™ delivery system to provide more effective and safer products, VAZALORE™ 325 mg and VAZALORE™ 81 mg (referred to together as "VAZALORE"™), announced today that the U.S. Food and Drug Administration ("FDA") is providing clarification for the regulatory path forward for VAZALORE.

Over the last year, the Company has refined and optimized its formulation, resulting in a high-quality and stable product. VAZALORE will deliver better absorption and improved GI safety for millions of patients at a high risk for cardiovascular events. In the Company's recent interactions with the FDA, PLx agreed to provide some additional data on VAZALORE 325 mg dose strength to bridge the new formulation to the original approved formulation, and expects to meet with the FDA to finalize the data modeling components shortly. In addition, PLx gained alignment with the FDA on the necessary data required for approval for the 81 mg dose. PLx anticipates completing the data modeling and the submissions for both the 325 mg and 81 mg simultaneously in the second quarter of 2020. It is projected that this will shift the timing of the launch of both dosages of VAZALORE in the United States towards the end of 2020.

Additionally, the FDA has approved updated labeling for 325 mg dose strength, and the Company will apply the approved 325 mg labeling to the 81 mg labeling in the CMC submission planned for second quarter 2020.

"We believe this valuable feedback from the FDA will result in a stronger submission with a higher likelihood of approval. The approval of our labeling for VAZALORE 325 mg is a great accomplishment and is vital to our continuing commercialization efforts," said Natasha Giordano, President and Chief Executive Officer of PLx Pharma.

About VAZALORE
VAZALORE 325 mg is an FDA-approved aspirin product being developed to provide patients with vascular disease and diabetic patients who are candidates for aspirin therapy with more reliable and predictable antiplatelet efficacy as compared to enteric-coated aspirin, while also reducing the adverse gastric events common in an acute setting. PLx is focused on manufacturing, scale-up and label finalization for VAZALORE 325 mg aspirin dosage form and preparing an sNDA for VAZALORE 81 mg maintenance dose form. Our goal is to begin selling both products in the United States towards the end of 2020, subject to approval by the FDA.

About PLx Pharma Inc.
PLx Pharma Inc. is a late-stage specialty pharmaceutical company focused on developing its clinically validated and patent-protected PLxGuard™ delivery system to provide more effective and safer products. The PLxGuard delivery system works by targeting delivery of active pharmaceutical ingredients (API) to various portions of the gastrointestinal (GI) tract. PLx believes this has the potential to improve the absorption of many drugs currently on the market or in development, and to reduce GI side effects—including erosions, ulcers and bleeding—associated with aspirin and ibuprofen, and potentially other drugs.

To learn more about PLx Pharma Inc. and its pipeline, please visit www.plxpharma.com.

Forward-Looking Statements
Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the prospects for commercializing or selling any products or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to PLx may identify forward-looking statements. PLx cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including the failure by PLx to secure and maintain relationships with collaborators; risks relating to clinical trials; risks relating to the commercialization, if any, of PLx's proposed product candidates (such as marketing, regulatory, product liability, supply, competition, and other risks); dependence on the efforts of third parties; dependence on intellectual property and risks that PLx may lack the financial resources and access to capital to fund proposed operations. Further information on the factors and risks that could affect PLx's business, financial conditions and results of operations are contained in PLx's filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Other risks and uncertainties are more fully described in PLx's Form 10-K for the year ended December 31, 2018 filed with the SEC on March 8, 2019, and in other filings that PLx will make going forward. The forward-looking statements represent PLx's estimate as of the date hereof only, and PLx specifically disclaims any duty or obligation to update forward-looking statements.

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