PLx Pharma Receives FDA Approval of SNDAs for Both VAZALORE 325 mg and 81 mg

March 1, 2021

-- VAZALORE is the first ever liquid-filled aspirin capsule with an innovative delivery platform indicated as a pain reliever, fever reducer and for aspirin therapy in vascular indications –

-- U.S. commercial launch of VAZALORE planned for third quarter 2021 --

SPARTA, N.J., March 01, 2021 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP) ("PLx" or the "Company") is a late-stage specialty pharmaceutical company focused on its clinically-validated and patent-protected PLxGuard™ drug delivery platform designed to provide more effective and safer products. PLx announced today that the U.S. Food and Drug Administration ("FDA") approved supplemental new drug applications ("sNDAs") for its lead products, VAZALORE™ 325 mg and VAZALORE™ 81 mg (referred to together as "VAZALORE"), the first ever novel, liquid-filled aspirin capsule.

"The approval of the VAZALORE sNDAs marks a significant milestone that brings us closer to providing an innovative aspirin to millions of patients who need reliable and predictable antiplatelet therapy," stated Natasha Giordano, President and Chief Executive Officer of PLx.

"We are delighted that the FDA approved both sNDAs for VAZALORE, and we are eager to implement our commercial launch plans later this year. We look forward to introducing VAZALORE to the medical community and to patients who can benefit from this breakthrough technology designed to reduce the risk of stomach injury," concluded Giordano.

In October 2020, the Company submitted separate supplemental new drug applications ("sNDAs") for each dose strength. The submissions were considered chemistry and manufacturing control ("CMC") filings as they included information on a change in formulation and the new manufacturing site for VAZALORE 325 mg and a new product strength for the 81 mg dose.

The submission for the 325 mg dose also contained the results of a clinical study, demonstrating VAZALORE's bioequivalence to immediate-release aspirin, further supporting the change in formulation. The submission for the 81 mg dose builds off the information in the original approved new drug application, as well as the recent sNDA submitted for VAZALORE 325 mg.

About VAZALORE
VAZALORE is an FDA-approved liquid-filled aspirin capsule that provides patients with vascular disease and diabetic patients who are candidates for aspirin therapy based on physician recommendation, with fast, reliable and predictable platelet inhibition as compared to enteric-coated aspirin. It also reduces the risk of stomach erosions and ulcers, as compared to immediate-release aspirin, common in an acute setting.

About PLx Pharma Inc.
PLx Pharma Inc. is a late-stage specialty pharmaceutical company focused on its clinically-validated and patent-protected PLxGuard™ drug delivery platform to provide more effective and safer products. The PLxGuard drug delivery platform works by targeting the release of active pharmaceutical ingredients to various portions of the gastrointestinal (GI) tract. PLx Pharma believes this has the potential to improve the absorption of many drugs currently on the market or in development, and to reduce the risk of stomach erosions and ulcers associated with certain 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, 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, 2019 filed with the SEC on March 13, 2020, and in other filings that PLx has made or 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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