PLx Pharma Inc. Submits Supplemental New Drug Applications for VAZALORE™ 325 mg and 81 mg to U.S. Food and Drug Administration

November 16, 2020

-- FDA sets estimated completion review date for the end of February 2021 --

-- Targeting launch of VAZALORE for third quarter 2021 –

SPARTA, N.J., Nov. 16, 2020 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP), 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, announced today that two chemistry and manufacturing control ("CMC") supplemental New Drug Applications ("sNDAs"), one for VAZALORE 325 mg and one for VAZALORE 81 mg dose (referred to together as "VAZALORE"), were submitted to the U.S. Food and Drug Administration ("FDA") in October for regulatory approval.

The 325 mg sNDA provided information on a change in formulation and a new manufacturing site for the currently approved VAZALORE and also contains a bioequivalence ("BE") clinical study report with the required data and analyses from the recently completed BE study. The submission for the 81 mg dose provided for a new product strength of VAZALORE and builds off the information in the original approved NDA (New Drug Application) and the recent sNDA submitted for VAZALORE 325 mg.

The Company received acknowledgement letters from the FDA, officially confirming the receipt of the submissions and setting the estimated completion date for its reviews for VAZALORE 325 mg and VAZALORE 81 mg for the end of February 2021. If approved, the Company plans to bring both doses of VAZALORE to market in the third quarter of 2021.

"We are delighted to have achieved this major milestone for the submissions of our two sNDAs to the FDA earlier than previously announced. This is a significant step for PLx and the millions of patients with vascular disease who can benefit from a novel aspirin therapy. We are highly confident our submissions are supported by strong and compelling data that FDA requires for CMC submissions and we look forward to their review," stated Natasha Giordano, President and Chief Executive Officer of PLx. "I'd also like to thank our teams and our partners for their extraordinary efforts preparing these filings and our shareholders for their support in advancing VAZALORE to regulatory review," concluded Giordano.

About VAZALORE
VAZALORE 325 mg is an FDA-approved liquid-filled aspirin capsule that provides patients with vascular disease and diabetic patients who are candidates for aspirin therapy with faster, reliable and more predictable platelet inhibition as compared to enteric-coated aspirin, while also reducing the risk of stomach erosions and ulcers, as compared to immediate-release aspirin, common in an acute setting. PLx's supplemental New Drug Applications for VAZALORE 325 mg and VAZALORE 81 mg dose strengths, submitted in October 2020 to the U.S. Food and Drug Administration, are currently under regulatory review.

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 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 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, 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.

Contact
Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793

E: lwilson@insiteconv.com

Source: PLx Pharma Inc.

Source: PLx Pharma Inc.