



PLx Pharma Inc. Presents Moderated Abstract and Simultaneous Publication on the Pharmacokinetic and Pharmacodynamics (PK/PD) Properties of its Novel, Liquid Aspirin Formulation at the 2019 European Society of Cardiology Congress

September 3, 2019

VAZALORE'S novel mechanism of action with an improved GI safety profile also delivers fast, reliable absorption and predictable antiplatelet effect establishing bioequivalence with regular aspirin.

SPARTA, N.J. and PARIS, Sept. 03, 2019 (GLOBE NEWSWIRE) -- PLx Pharma Inc. (NASDAQ: PLXP) ("PLx" or the "Company"), a late-stage specialty pharmaceutical company focused on developing more effective and safer products with its patent-protected PLxGuard™ delivery system announced today the presentation of a moderated poster on VAZALORE™ 325 mg at the 2019 European Society of Cardiology (ESC) Congress, the largest global gathering of cardiovascular experts and the simultaneous publication in the *Journal of Thrombosis and Thrombolysis*.

Abstract Title: Pharmacokinetic and pharmacodynamic assessment of a lipid-based aspirin formulation: results of a prospective, randomized, crossover study

Session Date: Sunday, September 1, 12:30 PM Central European Time

Presenter: Dominick J. Angiolillo, MD, PhD, FACC, FESC, FSCAI, Program Director, Interventional Cardiology Fellowship, Professor of Medicine, Director, Cardiovascular Research, University of Florida College of Medicine-Jacksonville, Jacksonville, FL, USA

The presentation was included in the *Evolving Developments in Anti-Platelet Therapy* program.

Study Design

In this active-control crossover study, 16 healthy volunteers were randomized to receive single doses of 325 mg or 650 mg of either immediate release aspirin or the novel pharmaceutical lipid-aspirin complex (i.e. VAZALORE) in a sequential fashion with a two-week washout period between treatment assignments. The primary objectives of the study were to assess pharmacokinetic (i.e., plasma salicylic acid levels) and pharmacodynamic PD (i.e., serum thromboxane B2 levels) bioequivalence over a 24-hour period. The results established both PK and PD bioequivalence between the two aspirin formulations according to FDA established criteria.

"The data presented at ESC demonstrate that VAZALORE, with its novel liquid formulation, can deliver fast and reliable aspirin absorption that is bioequivalent to that seen with immediate release aspirin. These findings, together with results from previous studies showing significant reductions in the risk for gastric erosions and ulcers with VAZALORE, suggest that this novel compound may confer a superior benefit risk profile compared with currently available aspirin options," stated Dr. Angiolillo, the lead author of the *Journal of Thrombosis and Thrombolysis* publication released simultaneously with the moderated poster presentation.

"Aspirin remains the cornerstone of lifelong antithrombotic protection for patients with established atherosclerotic cardiovascular disease. Our data presented here complement previous studies with this lipid-based formulation of aspirin. It is encouraging that a new aspirin formulation combining reliable absorption and antiplatelet efficacy with improved GI safety may soon be available to our patients," added Deepak L. Bhatt, MD, MPH, FACC, FAHA, FSCAI, FESC, Executive Director of Interventional CV Programs Brigham and Women's Hospital Heart & Vascular Center, Professor of Medicine, Harvard Medical School.

"We are thrilled to partner with our academic colleagues and generate such high-quality data that establishes the performance of our novel, liquid aspirin formulation, VAZALORE. We believe that VAZALORE has the potential to address the long-standing need for a new, better aspirin product with reliable efficacy and improved safety. We remain focused on our efforts to make VAZALORE available as soon as possible to the millions of high-risk cardiovascular patients who require reliable lifelong vascular protection," concluded Efthymios Deliargyris, MD, FACC, FESC, FSCAI, Chief Medical 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 by mid-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](http://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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