European Commission Grants Conditional Marketing Authorization for Portola Pharmaceuticals' Ondexxya™ (andexanet alfa), the First and Only Antidote for the Reversal of Factor Xa Inhibitors

April 26, 2019

– Major Advance in the Treatment of European Factor Xa Inhibitor Patients Hospitalized with Life-Threatening Bleeding –

– Initial Launch in Select Countries to Begin 2H 2019 –

SOUTH SAN FRANCISCO, Calif., April 26, 2019 (GLOBE NEWSWIRE) -- Portola Pharmaceuticals, Inc.® (Nasdaq: PTLA) today announced that the European Commission (EC) has granted conditional Marketing Authorization for Ondexxya™ (andexanet alfa). Ondexxya is the first and only antidote approved in Europe for adult patients treated with the Factor Xa inhibitor apixaban or rivaroxaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

"The medical community has been eagerly anticipating the approval of Ondexxya and the ability to rapidly reverse the anticoagulating effects of rivaroxaban or apixaban," said Jan Beyer-Westendorf, M.D., Head of the Thrombosis Research Unit, Department of Medicine I; Division Hematology, University Hospital Dresden, Germany. "As the number of European patients prescribed these Factor Xa inhibitors continues to increase, so too does the incidence of hospital admissions related to bleeding. The approval of Ondexxya represents a significant step forward in the treatment of these patients, who previously had no approved treatment option."

The conditional approval of Ondexxya was based on data from two Phase 3 ANNEXA studies (ANNEXA-R and ANNEXA-A) that evaluated the safety and efficacy of Ondexxya in reversing the anticoagulant activity of the Factor Xa inhibitors rivaroxaban or apixaban in healthy subjects, and data from the Phase 3b/4 ANNEXA-4 study that evaluated efficacy and safety data from 352 bleeding patients. Results from all three studies were published in *The New England Journal of Medicine* – ANNEXA-R and ANNEXA-A in 2015, and ANNEXA-4 in February 2019.

"The unmet need for a reversal agent in Europe is significant, as the number of patients taking a Factor Xa inhibitor is nearly double that of the U.S. and continuing to grow at a significant rate. To help ensure we reach as many patients as quickly as possible, our initial launch efforts will be focused on a select group of countries where Factor Xa use is among the highest," said Scott Garland, Portola's president and chief executive officer. "We are very proud that, in just one year, we have achieved both U.S. and European approval of this potentially life-saving medicine and look forward to continuing to expand patient access in these countries and beyond."

The EC grants conditional authorizations to medicines that fulfill a medical need and show a potential benefit to public health, and for which additional data are required by the EC. As part of the conditional approval, Portola will provide the final study reports for both the ANNEXA-4 trial and the randomized controlled clinical trial requested by the U.S. Food and Drug Administration (FDA), as well as additional pharmacokinetic data.

Ondexxya was approved by the FDA in May 2018 and is marketed by Portola in the U.S. under the trade name Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo].

Important Safety Information
The most frequently reported adverse reactions in clinical trials in healthy subjects with Ondexxya were mild or moderate infusion-related reactions comprising symptoms such as flushing and feeling hot (very common), and cough, dysgeusia, and dyspnoea (common). Amongst bleeding patients, commonly reported side effects were ischaemic stroke and pyrexia, with uncommonly reported side effects of cerebral infarction, cerebrovascular accident, transient ischaemic attack, acute myocardial infarction, cardiac arrest, myocardial infarction, deep vein thrombosis, iliac artery occlusion, pulmonary embolism.

Please refer to full SmPC for further information on side effects reported with Ondexxya.

The U.S. full prescribing information for Andexxa is available at www.andexxa.com

About Portola Pharmaceuticals, Inc.
Portola Pharmaceuticals is a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics that could significantly advance the fields of thrombosis and other hematologic diseases. The Company's two FDA-approved medicines are Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo], the first and only antidote for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, and Bevyxxa® (betrixaban), the first and only oral, once-daily Factor Xa inhibitor for the prevention of VTE in adult patients hospitalized for an acute medical illness. The company also is advancing cerdulatinib, a Syk/JAK inhibitor for the treatment of hematologic cancers.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the anticipated launch timing and strategy for Ondexxya in Europe and potential treatment benefits of Ondexxya. Risks that contribute to the uncertain nature of the forward-looking statements include: the risk that physicians, patients and payers may not see the benefits of utilizing Ondexxya for the indications which they are approved; our ability to continue to manufacture our products and to expand approved manufacturing facilities; the possibility of unfavorable results from additional clinical trials involving Andexxa; the risk that Portola may not obtain additional regulatory approvals necessary to expand approved indications for Andexxa; our expectation that we will incur losses for the foreseeable future and will need additional funds to finance our operations; the accuracy of our estimates regarding expenses and capital requirements; our ability to successfully build a hospital-based sales force and commercial infrastructure; our ability to obtain and maintain intellectual property protection for our product candidates; and our ability to retain key scientific or management personnel. These and other risks and uncertainties are described more fully in our most recent filings with the Securities and Exchange Commission, including our most recent annual report on Form 10-K. All forward-looking statements contained in this press release speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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