Portola Pharmaceuticals Receives and Plans to Appeal Negative CHMP Opinion Regarding Marketing Authorization for Betrixaban in the European Union

SOUTH SAN FRANCISCO, Calif., March 23, 2018 (GLOBE NEWSWIRE) -- Portola Pharmaceuticals, Inc.® (Nasdaq:PTLA) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a negative opinion for betrixaban for the prevention of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness with risk factors for VTE, including VTE-related death. The Company intends to appeal the opinion and seek a re-examination by the CHMP.

“We believe we have generated substantial evidence which demonstrates the clinically-meaningful benefit of betrixaban in reducing VTE and VTE-related deaths in this vulnerable patient population, and we remain confident in its potential to have a major public health impact,” said Jack Lawrence, M.D., chief medical officer of Portola. “The re-examination process allows us the opportunity to address the CHMP’s questions and provide further clarification as needed, with the goal of making betrixaban available to acute medically ill patients in Europe who are at risk for VTE.”

The Marketing Authorization Application (MAA) for betrixaban included data from Portola’s pivotal Phase 3 APEX Study, which enrolled 7,513 patients at more than 450 clinical sites worldwide. The APEX study evaluated oral betrixaban from hospital admission to home (35 to 42 days) compared with injectable enoxaparin for 6 to 14 days followed by placebo in assessing the prevention of VTE in high-risk acutely ill medical patients.

Betrixaban was approved by the U.S. Food and Drug Administration in June 2017 under the trade name Bevyxxa®.

About Portola Pharmaceuticals, Inc.
Portola Pharmaceuticals is a biopharmaceutical company developing product candidates that could significantly advance the fields of thrombosis and other hematologic diseases. The Company’s first medicine Bevyxxa® (betrixaban), an oral, once-daily Factor Xa inhibitor, was approved by the U.S. Food and Drug Administration in June 2017. The company is also working to advance two clinical programs for andexanet alfa, a recombinant protein designed to reverse the anticoagulant effect in patients treated with an oral or injectable Factor Xa inhibitor; and cerdulatinib, a SYK/JAK inhibitor in development to treat hematologic cancers. Portola's partnered program is focused on developing selective SYK inhibitors for inflammatory conditions. For more information, visit http://www.portola.com and follow the Company on Twitter @Portola_Pharma.

Forward-Looking Statements
This announcement contains forward-looking statements, including statements relating to Portola

Pharmaceuticals' expectations regarding the regulatory status of betrixaban. These statements are subject to significant risks and uncertainties and actual results could differ materially from those projected. Portola Pharmaceuticals cautions investors not to place undue reliance on the forward-looking statements contained in this release. These risks and uncertainties include, without limitation, risks and uncertainties related to the regulatory status of betrixaban in Europe. Risks and uncertainties relating to Portola Pharmaceuticals and its business can be found in the "Risk Factors" section of Portola Pharmaceuticals' Annual Report on Form 10-K for 2017, which was filed with the SEC on March 1, 2018 . Portola Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in Portola Pharmaceuticals' expectations.

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Portola Pharmaceuticals, Inc.

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