Portola Pharmaceuticals Announces AndexXa® (Andexanet Alfa) Biologics License Application Resubmission Accepted for Review by U.S. FDA

SOUTH SAN FRANCISCO, Calif., Aug. 15, 2017 (GLOBE NEWSWIRE) -- Portola Pharmaceuticals Inc.® (Nasdaq:PTLA) today announced that the U.S. Food and Drug Administration (FDA) has found its resubmitted Biologics License Application (BLA) for AndexXa® (andexanet alfa) to be acceptable for review, with an action due date of February 2, 2018.

The resubmission includes supplemental information primarily related to analytics and manufacturing, as requested by the FDA in a complete response letter issued to Portola last year.

Portola is developing AndexXa as a universal reversal agent for patients anticoagulated with an oral or injectable Factor Xa inhibitor who experience a serious uncontrolled or life-threatening bleeding event or who require urgent or emergency surgery. The BLA seeks initial approval of AndexXa for reversal of the anticoagulant effects of apixaban and rivaroxaban in patients experiencing uncontrolled or life-threatening bleeding.

In 2016, approximately 90,000 patients in the U.S. treated with oral Factor Xa inhibitors were subsequently admitted to the hospital due to bleeding. Including patients taking the injectable Factor Xa inhibitor enoxaparin, it is estimated that more than 150,000 U.S. patients could benefit from an antidote annually. Currently, there are no approved Factor Xa inhibitor antidotes.

About AndexXa (Andexanet Alfa)
AndexXa (andexanet alfa), an investigational drug, is a modified human Factor Xa molecule that acts as a decoy to target and sequester with high specificity both oral and injectable Factor Xa inhibitors in the blood. Once bound, the Factor Xa inhibitors are unable to bind to and inhibit native Factor Xa, thus potentially allowing for the restoration of normal hemostatic processes. AndexXa is the first compound being studied as an antidote for Factor Xa inhibitors that directly and specifically reverses anti-Factor Xa activity, the anticoagulant mechanism of these agents.

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 AndexXa (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

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, AndexXa’s potential as a Factor Xa inhibitor antidote and the projected response time of the FDA to the resubmission of our BLA for AndexXa. Risks that contribute to the uncertain nature of the forward-looking statements include: failure to obtain FDA and/or EMA approval for AndexXa, regulatory developments in the United States and foreign countries; our potential inability to manufacture our product candidates on a commercial scale in a timely or cost-efficient manner; 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 quarterly report on Form 10-Q. 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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