# Portola Pharmaceuticals Submits Prior Approval Supplement to U.S. FDA for Large-Scale Generation 2 Andexxa Process

SOUTH SAN FRANCISCO, Calif., Aug. 31, 2018 (GLOBE NEWSWIRE) -- Portola Pharmaceuticals, Inc.® (Nasdaq:PTLA) today announced the submission of a prior approval supplement (PAS) to the U.S. Food and Drug Administration (FDA) for the large-scale Generation 2 manufacturing process for Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo]. If approved, the PAS will allow for broad commercial launch of Andexxa in the United States.

Andexxa received both U.S. Orphan Drug and FDA Breakthrough Therapy designations, and was approved on May 3, 2018 under the FDA's Accelerated Approval pathway. It is the first and only antidote indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

“We are pleased that patients are already benefitting from access to our limited supply Generation 1 product via an Early Supply Program,” said John Curnutte, M.D., Ph.D., interim co-president of Portola and head of research and development. “With the recent completion of three successful Generation 2 manufacturing campaigns, we have enough supply to stock more than 1,000 hospitals, and we look forward to working with regulatory authorities to achieve our goal of expanding patient access to this potentially life-saving medicine.”

Based on FDA timelines, the Company expects a final decision on the PAS in Q1 2019. In Europe, andexanet alfa received a positive trend vote from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency in February 2018. Pending the submission of additional data requested by the CHMP, a final CHMP opinion is expected in Q4 2018 with the potential for approval in Q1 2019.

**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 and 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 timelines for regulatory review of our PAS and CHMP opinion in Europe and our ability to supply more than 1,000 hospitals with Generation 2 product, as well as expanding patient access and the medical and commercial potential of Andexxa. 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 Andexxa or Bevyxxa for the indications which they are approved; the risk that the FDA may not accept our PAS for review, may not approve our PAS on anticipated timelines, or at all and the risk that the FDA may require additional data before approving our Generation 2 manufacturing process; 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 the EMA may not approve Andexxa in the currently anticipated timelines or at all, and that any marketing approvals or reimbursement limitations may have significant limitations on its use; the risk that we 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 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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