Portola Investor Room

Portola Launches European Sales of Ondexxya® (Andexanet Alfa) with First Orders in Europe

- Expands Patient Access to the First and Only Factor Xa Reversal Agent Approved in Europe for Life-Threatening Bleeds Associated with the Use of Rivaroxaban or Apixaban -

SOUTH SAN FRANCISCO, Calif., Aug. 6, 2019 /PRNewswire/ -- Portola Pharmaceuticals, Inc.® (Nasdaq: PTLA) today announced the Company's first sales of Ondexxya® (andexanet alfa) in Europe. These sales mark the initiation of commercial access in Europe to Ondexxya – the first and only reversal agent approved for adult patients treated with the Factor Xa inhibitors rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Portola is executing a phased launch of Ondexxya in Europe, with an initial focus on Germany, Austria, the United Kingdom, the Netherlands, Sweden, Denmark and Finland, where Factor Xa inhibitor use, and related bleeds, are among the highest in Europe.

"The number of Europeans taking a Factor Xa inhibitor is nearly double that of the U.S. and continues to grow at a significant rate. The speed with which these first European orders were received and the number of medical societies that have already added Ondexxya to their guidelines speaks to the potential unmet need and demand for Ondexxya," said Scott Garland, Portola's president and chief executive officer. "We are pleased to now be providing European clinicians with this important new medicine and to have the opportunity to impact hundreds of thousands of lives."

"As the first and only Factor Xa reversal agent approved in Europe to address life-threatening bleeds associated with apixaban or rivaroxaban, Ondexxya represents a significant step forward in patient care," said Gerwin Winter, senior vice president and Portola's head of Europe. "We look forward to continuing discussions with individual reimbursement authorities and further expanding access to Ondexxya in Europe."

The worldwide use of Factor Xa inhibitors is rapidly growing because of their efficacy and safety profile compared to warfarin and enoxaparin in preventing and treating thromboembolic conditions such as stroke, pulmonary embolism and venous thromboembolism (VTE). This growth has come with a related increase in the incidence of hospital admissions and deaths related to bleeding, the major complication of anticoagulation. Prior to its approval in Europe, international guidelines from the American College of Chest Physicians (CHEST) and the European Society of Cardiology (ESC) recommended Ondexxya for first-line use based on its clinical attributes. Ondexxya is now recognized in nine European medical society guidelines, including the European Stroke Organisation.

The European Commission (EC) granted conditional Marketing Authorization for Ondexxya in Europe in April 2019. It was approved by the U.S. Food and Drug Administration (FDA) in May 2018 under the FDA's Accelerated Approval pathway and is marketed by Portola in the U.S. under the trade name Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo].

About Ondexxya
Ondexxya is a recombinant protein specifically designed to bind to Factor Xa inhibitors and rapidly reverse their anticoagulant effect. Ondexxya is a modified form of the human Factor Xa molecule, an enzyme that helps blood clot. It works by acting as a decoy for oral and injectable Factor Xa inhibitors, which target and bind to Factor Xa. When Ondexxya is given to a patient with Factor Xa inhibitor-related bleeding, it binds to the Factor Xa inhibitor and prevents it from inhibiting the activity of Factor Xa and reverses the anticoagulant effects of the inhibitor.

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

For additional Important Safety Information and Andexxa's full Prescribing Information, please visit

http://www.Andexxa.com.

IMPORTANT INFORMATION FOR ANDEXXA [coagulation factor Xa (recombinant), inactivated-zhzo]

BOXED WARNING: THROMBOEMBOLIC RISKS, ISCHEMIC RISKS, CARDIAC ARREST AND SUDDEN DEATHS

See full prescribing information for complete boxed warning

Treatment with Andexxa has been associated with serious and life-threatening adverse events, including:

- **Arterial and venous thromboembolic events**
- **Ischemic events, including myocardial infarction and ischemic stroke**
- **Cardiac arrest**
- **Sudden deaths**

Monitor for thromboembolic events and initiate anticoagulation when medically appropriate. Monitor for symptoms and signs that precede cardiac arrest and provide treatment as needed.

About Portola Pharmaceuticals, Inc.
Portola Pharmaceuticals is a global, 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 conditions. The Company's first two commercialized products are Andexxa [coagulation factor Xa (recombinant), inactivated-zhzo], marketed in Europe as Ondexxya (andexanet alfa), and Bevyxxa® (betrixaban). The company also is advancing cerdulatinib, a SYK/JAK inhibitor being developed for the treatment of hematologic cancers. Founded in 2003 in South San Francisco, California, Portola has operations in the United States and Europe.

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 it is 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 Ondexxya; the risk that Portola may not obtain additional regulatory approvals necessary to expand approved indications for Ondexxya; 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 products and 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 and 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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