

Portola Pharmaceuticals Announces New APEX Study Sub-Analyses Data to be Presented at American Heart Association Scientific Sessions 2016

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Portola Pharmaceuticals Inc.[®] (Nasdaq:PTLA) today announced that results of new sub-analyses of the Phase 3 APEX Study of betrixaban, conducted by Dr. C. Michael Gibson and the PERFUSE Study Group, will be presented in oral and poster sessions at the upcoming American Heart Association (AHA) Scientific Sessions 2016, which is taking place from November 12-16 in New Orleans.

Betrixaban, a U.S. Food and Drug Administration (FDA) Fast Track-designated investigational drug, is an oral, once-daily Factor Xa inhibitor anticoagulant in development for the prevention of venous thromboembolism (VTE) in acute medically ill patients. Portola submitted a New Drug Application to the FDA in October 2016 seeking approval to market betrixaban for extended-duration prophylaxis of VTE in acute medically ill patients with risk factors for VTE. Portola expects a response from the FDA within 60 days as to whether the NDA is complete and acceptable for filing.

Following are details of the oral and poster presentations, which will include additional data not available in the abstracts. AHA will post the abstracts on Friday, November 11, at 4:00 p.m. ET at <http://www.abstractsonline.com/pp8/#!/4096>.

Oral Presentations

- Abstract Title: Betrixaban reduces the burden of multiple symptomatic venous thromboembolic events in the APEX trial

Abstract #: 640

Presenting Author: Purva Jain, M.P.H., biostatistician, PERFUSE Study Group, Beth Israel Deaconess Medical Center, Boston

Session Title: Hemostasis, Thrombosis and Fibrinolysis

Presentation Date and Time: Monday, November 14, 10:30 -10:35 a.m. CT

Presentation Location: Science and Technology Hall, Basic Science Theater

- Abstract Title: Extended duration betrixaban reduces the risk of stroke vs standard dose enoxaparin among hospitalized medically ill patients: An APEX substudy

Abstract #: 277

Presenting Author: C. Michael Gibson, M.S., M.D., APEX Executive Committee Member and Steering Committee Chairman; professor, Harvard Medical School; chairman, PERFUSE Study Group, Beth Israel Deaconess Medical Center, Boston

Session Title: Sol Sherry Distinguished Lecture in Thrombosis

Presentation Date and Time: Monday, November 14, 3:15-3:25 p.m. CT

Presentation Location: Room 217

Poster Presentation

- Abstract Title: IMPROVEDD Score: Addition of D-dimer to the IMPROVE score improves venous thromboembolism risk stratification: An APEX trial substudy

Abstract #: T1201/1201

Presenting Author: Gerald Chi, M.D., PERFUSE Study Group, Beth Israel Deaconess Medical Center, Boston

Session Title: Hemostasis, Thrombosis and Fibrinolysis

Presentation Date and Time: Tuesday, November 15, 12:45-2:00 p.m. CT

Presentation Location: Science and Technology Hall, Basic Science Section

About the APEX Study

The pivotal Phase 3 APEX Study enrolled 7,513 patients at more than 450 clinical sites worldwide and assessed the superiority of extended-duration anticoagulation with oral betrixaban for 35-42 days compared with standard-duration injectable enoxaparin for 10+4 days in preventing VTE in high-risk acute medically ill patients. Full study results were presented at the 62nd Annual International Society on Thrombosis and Haemostasis (ISTH) Scientific and Standardization Committee (SSC) Meeting in May 2016 and published simultaneously online in [The New England Journal of Medicine](#).

About Betrixaban

Betrixaban, an investigational drug, directly inhibits the activity of Factor Xa, an important validated target in the blood coagulation pathway, to prevent life-threatening thrombosis. Betrixaban has distinct properties that may allow it to demonstrate clinical benefit without the significant imbalance in the risk of major bleeding seen with other agents in the class. These include a 19-25-hour half-life for once-daily dosing; a low peak-to-trough drug concentration ratio that minimizes anticoagulant variability; low renal clearance; and no significant CYP3A4 metabolism, which may reduce the risk of drug-drug interactions.

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 is advancing three programs, including betrixaban, an oral, once-daily Factor Xa inhibitor; 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 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, statements regarding development of our product candidates, our regulatory applications and estimated timelines associated therewith. Risks that contribute to the uncertain nature of the forward-looking statements include: failure to obtain regulatory approval for one or more of our product candidates, our expectation that we will incur losses for the foreseeable future and will need additional funds to finance our operations; the results of our clinical trials related to the efficacy and safety of our product candidates; our potential inability to manufacture our product candidates on a commercial scale in a timely or cost-efficient manner; the accuracy of our estimates regarding expenses and capital requirements; regulatory developments in the United States and foreign countries; 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, which was filed on August 9, 2016. 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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Portola Pharmaceuticals, Inc.



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