TESARO Announces Updates to the U.S. Prescribing Information for VARUBI® (rolapitant) Injectable Emulsion

January 12, 2018

WALTHAM, Mass., Jan. 12, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced that it has updated the VARUBI® (rolapitant) injectable emulsion package insert in collaboration with the U.S. Food and Drug Administration (FDA). VARUBI injectable emulsion is a substance P/neurokinin (NK-1) receptor antagonist indicated for the prevention of delayed nausea and vomiting associated with chemotherapy in adults. The changes to the labeling include modifications to the CONTRAINDICATIONS, WARNINGS and PRECAUTIONS, and ADVERSE REACTIONS sections.

Following its introduction in late November 2017, TESARO estimates that at least 7,000 doses of VARUBI injectable emulsion have been administered to patients receiving emetogenic chemotherapy in the United States. Anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions have been reported in the postmarketing setting, some requiring hospitalization. These reactions have occurred during or soon after the infusion of VARUBI injectable emulsion. Most reactions have occurred within the first few minutes of administration.

Patient safety is a paramount priority for TESARO. In its commitment to ensuring patients and healthcare professionals are aware of the label update, TESARO has issued a Dear Healthcare Professional (DHCP) letter. This letter, as well as the updated full prescribing information, has been posted on the VARUBI website (www.varubirx.com). Additionally, members of the TESARO field force will be calling on healthcare professionals to communicate this important new safety information.

Healthcare providers and patients are encouraged to report adverse events in patients taking VARUBI injectable emulsion to TESARO at 1-844-4-TESARO (1-844-483-7276). TESARO's medical information department may be reached at 1-844-4- TESARO (1-844-483-7276) to address any questions from healthcare providers about the information contained in this release, or the safe and effective use of VARUBI injectable emulsion.

VARUBI Indication and Important Safety Information

VARUBI, in combination with other antiemetic agents, is indicated in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

VARUBI is contraindicated in patients taking CYP2D6 substrates with a narrow therapeutic index, such as thioridazine and pimozide. VARUBI can significantly increase the plasma concentrations of thioridazine and pimozide, which may result in QT prolongation and Torsades de Pointes.

VARUBI is a moderate inhibitor of CYP2D6 and significantly increases the plasma concentrations of CYP2D6 substrates for at least 28 days, with inhibitory effects expected to persist for an unknown duration. Monitor for adverse reactions when VARUBI is coadministered with CYP2D6 substrates without a narrow therapeutic index (avoid coadministration with CYP2D6 substrates with a narrow therapeutic index, thioridazine and pimozide; see Contraindication).

In clinical trials, the most common adverse reactions reported were neutropenia, hiccups, decreased appetite and dizziness. IV administration of VARUBI was also associated with infusion-related symptoms (e.g., sensation of warmth, abdominal pain, dizziness, and paresthesia).

Avoid use of VARUBI in patients who require chronic administration of strong CYP3A4 inducers (e.g., rifampin), as significantly reduced plasma concentrations of VARUBI can decrease the efficacy of VARUBI.

VARUBI given as an oral dose is an inhibitor of breast cancer resistance protein (BCRP) and P-glycoprotein (P-gp). Increased plasma concentrations of BCRP substrates (e.g., methotrexate, topotecan, or irinotecan) and P-gp substrates (e.g., digoxin) with a narrow therapeutic index may result in potential adverse reactions. Monitor digoxin concentrations with concomitant use of VARUBI, and adjust the dosage as needed to maintain therapeutic concentrations.

Monitor INR and prothrombin time and adjust the dosage of warfarin, as needed, to maintain target INR.

VARUBI is available by prescription only. Please see full prescribing information, including additional important safety information, available at www.varubirx.com.

About TESARO

TESARO is an oncology-focused biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. For more information, visit www.tesarobio.com, and follow us on Twitter and LinkedIn.

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Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding TESARO, they are forward-looking statements reflecting the current beliefs, estimates and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify such forward-looking statements. For example, the information in this press release relating to the Company's estimate of the number of doses of VARUBI® injectable emulsion administered is a forward-looking statement reflecting the current belief and best estimate of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This statement and other forward-looking statements contained herein involve substantial risks and uncertainties including, among others, risks and uncertainties associated with the completion of the integrated audit of the Company's financial statements for the year ended December 31, 2017 and the quarter ending March 31, 2018. Our estimate of the number of doses of VARUBI® injectable emulsion administered should not be used to extrapolate or estimate potential revenues from sales of VARUBI injectable emulsion for such periods, as the determination of such revenues is subject to a number of risks, uncertainties, and estimates which are unknown, including estimates of product returns. Accordingly, any estimates of revenues for such period would be highly speculative and unreliable. TESARO undertakes no obligation to update or revise any such forward-looking statements. For a further description of the risks and uncertainties relating to the business of the Company in general, see TESARO's Annual Report on Form 10-K for the year ended December 31, 2016, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2017.


Primary Logo

Source: TESARO, Inc.