TESARO Announces Third-Quarter 2017 Operating Results

November 7, 2017

- **ZEJULA® was the most prescribed PARP inhibitor in U.S. with Q3 net sales of $39.4 million**
- **Positive CHMP opinion issued for ZEJULA in E.U.; commercial launch anticipated to begin by year-end**
- **Expansion of niraparib development program underway for multiple tumor types**
- **VARUBI® IV approved by U.S. FDA; commercial launch planned for November**
- **Phase 1 combination study of TSR-022 (anti-TIM-3) and TSR-042 (anti-PD-1) now enrolling patients**
- **Phase 1 study of TSR-033 (anti-LAG-3) now enrolling patients**

WALTHAM, Mass., Nov. 07, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for third-quarter 2017 and provided an update on the Company's commercial products and development programs.

“Exiting the third quarter, ZEJULA achieved 60% market share of the ovarian cancer patient population treated with a PARP inhibitor. This is a result of our team’s solid execution, and is supported by the feedback from physicians and patients, which continues to be excellent with regards to the benefit ZEJULA provides for women living with ovarian cancer,” said Lonnie Moulder, CEO of TESARO. “Looking ahead, we are actively preparing for two additional product launches in 2017 — ZEJULA inEurope and VARUBI IV in the U.S. — and expanding our niraparib development programs to broaden its use with the PRIMA Phase 3 first line ovarian cancer study and the initiation of multiple combination studies in ovarian, lung, and breast cancer. We are rapidly advancing our pipeline of immuno-oncology candidates with three antibodies now in the clinic, and we are excited about the potential for the combination of TSR-022 and TSR-042 to meaningfully benefit patients with advanced solid tumors.”

Recent Business Highlights

- On October 25, 2017, the U.S. Food and Drug Administration (FDA) approved the intravenous (IV) formulation of VARUBI® (rolapitant), and the U.S. commercial launch is planned for November. The unit demand for VARUBI oral capsules increased 74% for Q3 2017 vs. Q3 2016, as the brand continues to penetrate the U.S. oral NK-1 market.
- ZEJULA® (niraparib) is the most prescribed PARP inhibitor in the U.S., with approximately 2,500 patients treated during the month of September.
- The European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for ZEJULA as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete response (CR) or partial response (PR) to platinum-based chemotherapy.
- Pre-launch preparations continue in support of a European launch of ZEJULA by year-end 2017 beginning with Germany, pending European Commission approval.
- The niraparib expanded access program (EAP) in Europe has enrolled more than 350 patients to date.
- Clinical trials were initiated to support planned Phase 3 studies of niraparib combined with our anti-PD-1 antibody, TSR-042, in patients with lung and ovarian cancers and to evaluate niraparib plus TSR-042 in patients with advanced or metastatic cancers suitable for treatment with an anti-PD-1 antibody, including ovarian and lung.
- Enrollment continues in the PRIMA trial of niraparib for patients with first-line ovarian cancer and the QUADRA trial of niraparib for the treatment of patients with ovarian cancer who have received three or more prior lines of chemotherapy.
- The Phase 2 TOPACIO trial of niraparib plus pembrolizumab is ongoing with additional data expected in 1H 2018. Preliminary Phase 2 data presented at ESMO showed activity in patients with platinum-resistant ovarian cancer and patients with triple-negative breast cancer.
- The Janssen GALAHAD Phase 2 efficacy and safety study of niraparib in men with metastatic castration-resistant prostate cancer and DNA-repair anomalies is ongoing to support a planned regulatory submission in 2019.
- Phase 1 data for TSR-042 (anti-PD-1 antibody) presented at ESMO demonstrated a predictable safety profile and clinical activity in heavily pre-treated patients. The GARNET registration trial of TSR-042 continues to enroll patients with metastatic microsatellite instability-high (MSI-H) cancers.
- To support initiation of planned Phase 3 studies, a clinical study was initiated to evaluate TSR-042 in combination with carboplatin-paclitaxel in patients with advanced or metastatic cancer.
- Enrollment continues in the Phase 1 AMBER combination study of TSR-022 (anti-TIM-3 antibody) plus TSR-042, and the Phase 1 CITRINO dose-escalation trial of TSR-033 (anti-LAG-3 antibody). Data from the monotherapy, dose-escalation portion of the AMBER trial of TSR-022 will be presented at the Society for Immunotherapy of Cancer (SITC) annual meeting on November 10.

Third Quarter 2017 Financial Results

TESARO reported total revenue of $142.8 million for the third quarter of 2017, compared to $17.0 million for the third quarter of 2016.

Net product revenue totaled $41.8 million for the third quarter of 2017, which included ZEJULA revenues of $39.4 million and VARUBI/VARUBY revenues of $2.4 million. This compares to net product revenue of $1.3 million for the third quarter of 2016.

License, collaboration, and other revenue totaled $101.0 million for the third quarter of 2017 and included the $100.0 million up-front payment received as part of the license agreement with Takeda. This compares to license, collaboration, and other revenue of $15.7 million for the third quarter of 2016, which included the majority of the $15.0 million up-front payment received as part of the Zai Lab license agreement.

Cost of sales totaled $7.5 million for the third quarter of 2017 and included $6.2 million associated with product revenue and $1.3 million related to amortization of milestones recorded upon FDA approval of ZEJULA and first commercial sales of VARUBI/VARUBY in the U.S. and Europe. Cost of sales totaled $0.8 million for the third quarter of 2016.

Research and development expenses increased to $73.4 million for the third quarter of 2017, compared to $60.8 million for the third quarter of 2016, driven primarily by increased headcount, the advancement of our earlier-stage immuno-oncology portfolio, and expansion of the TSR-042 and TSR-022 programs.

Selling, general and administrative expenses increased to $84.0 million for the third quarter of 2017, compared to $37.7 million for the third quarter of 2016, primarily due to increased headcount, activities in support of the launches of ZEJULA and VARUBY in the U.S. and Europe, and higher professional service fees.

Operating expenses as described above include total non-cash, stock-based compensation expense of $25.0 million for the third quarter of 2017, compared to $12.9 million for the third quarter of 2016.

Net loss totaled $25.3 million, or ($0.47) per share, for the third quarter of 2017, compared to a net loss of $87.9 million, or ($1.72) per share, for the third quarter of 2016.

As of September 30, 2017, TESARO had approximately $521.3 million in cash and cash equivalents and approximately 54.4 million outstanding shares of common stock.

Corporate Objectives

TESARO intends to achieve the following key objectives:

Commercial Products:

- Continue to execute on the ongoing U.S. launch of ZEJULA and solidify its position as the market-leading PARP inhibitor for patients with recurrent ovarian cancer;
- Launch ZEJULA in Europe by year-end 2017, pending European Commission approval; and
- Launch VARUBI IV in the U.S.

Pipeline Candidates:

- Rapidly advance the GARNET registration trial of TSR-042 in MSI-H cancers, with the intent of supporting accelerated FDA approval;
- Define the registration path in platinum-resistant ovarian cancer and triple negative breast cancer in Q1 2018, pending data from TOPACIO trial;
- Report initial data for the AMBER trial of TSR-022 in combination with TSR-042 in 2018;
- Complete the dose escalation phase of the TSR-033 CITRINO trial and in early 2018 initiate a combination trial of TSR-033 plus TSR-042;
- Initiate OVARIO, a Phase 2 clinical trial of niraparib in combination with bevacizumab in patients with first-line ovarian cancer by year end;
- Initiate a Phase 3 clinical trial of niraparib in combination with TSR-042 in first-line ovarian cancer in 1H 2018; and
- Initiate a Phase 3 clinical trial of niraparib in combination with TSR-042 in NSCLC in 2H 2018.

Today's Conference Call and Webcast
TESARO will host a conference call to discuss the Company's third quarter operating results and provide an update on the Company's commercial products and development programs today at 4:15 P.M. Eastern time. The accompanying slide presentation and live webcast of the conference call can be accessed by visiting the TESARO website at www.tesarobio.com. The call can be accessed by dialing (877) 853-5334 (U.S. and Canada) or (970) 315-0307 (international). A replay of the webcast will be archived on the Company's website for 30 days following the call.

About ZEJULA (Niraparib)
ZEJULA (niraparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. In preclinical studies, ZEJULA concentrates in the tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumor effect. Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including some fatal cases, was reported in patients treated with ZEJULA. Discontinue ZEJULA if MDS/AML is confirmed. Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia), as well as cardiovascular effects (hypertension and hypertensive crisis) have been reported in patients treated with ZEJULA. Monitor complete blood counts to detect hematologic adverse reactions, as well as to detect cardiovascular disorders, during treatment. ZEJULA can cause fetal harm and females of reproductive potential should use effective contraception. Please see full prescribing information, including additional important safety information,

available at www.zejula.com.

About VARUBI® (rolapitant)
VARUBI is a substance P/neurokinin-1 (NK-1) receptor antagonist indicated in combination with other antiemetic agents 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. NK-1 receptors are highly concentrated in the brain and bind neurokinin substance P. Activation of NK-1 receptors plays a central role in nausea and vomiting induced by emetogenic stimuli, including certain cancer chemotherapies. A Positron Emission Tomography (PET) study with rolapitant in normal, healthy volunteers demonstrated that rolapitant crosses the blood brain barrier and occupies brain NK-1 receptors at high levels for up to 120 hours. VARUBI has a half-life of approximately seven days, which may contribute to the ability of a single dose of VARUBI to cover the entire delayed CINV Phase (25-120 hours). 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 co-administered with CYP2D6 substrates without a narrow therapeutic index (avoid co-administration 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. Oral VARUBI 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.

TESARO Contacts:
Jennifer Davis
Vice President, Corporate Communications & Investor Relations
+1.781.325.1116 or jdavis@tesarobio.com

Kate Rausch
Associate Director, Investor Relations
+1.781.257.2505 or krausch@tesarobio.com

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 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 forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements regarding the expected timing of the launch of VARUBI IV in the U.S., the expected timing of our planned commercial launch of ZEJULA in Europe, the design and expected timing of initiation and data from our various ongoing and planned niraparib, TSR-042, TSR-033, TSR-022, combination, and other clinical trials, and our expectation to achieve our various key corporate objectives. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and pre-clinical development programs, clinical development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others risks related to competition, the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding our ongoing discussions with and potential actions by regulatory authorities, uncertainties regarding regulatory approvals, uncertainties regarding certain expenditures, risks related to manufacturing and supply, risks related to intellectual property, and other matters that could affect the availability or commercial potential of our products and drug candidates. TESARO undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2017.

TESARO, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2017	2016	2017
	(as revised)(1)		(as revised)(1)	
Revenues:				
Product revenue, net:				
ZEJULA®	$ -	$ 39,375	$ -	$ 65,321
VARUBI®/VARUBY®	1,326	2,380	2,844	7,402

Total product revenue, net	1,326	41,755	2,844	72,723
License, collaboration and other revenues	15,661	101,011	50,253	102,580
Total revenues	16,987	142,766	53,097	175,303
Expenses:				
Cost of sales - product	378	6,216	691	10,280
Cost of sales - intangible asset amortization	464	1,254	1,391	4,723
Research and development (2)	60,783	73,388	163,630	210,910
Selling, general and administrative (2)	37,685	83,998	104,052	246,239
Acquired in-process research and development	1,940	-	9,940	7,000
Total expenses	101,250	164,856	279,704	479,152
Loss from operations	(84,263)	(22,090)	(226,607)	(303,849)
Interest and other income (expense), net	(3,587)	(3,048)	(11,377)	(9,941)
Loss before income taxes	(87,850)	(25,138)	(237,984)	(313,790)
Provision for income taxes	-	139	-	271
Net loss	$ (87,850)	$ (25,277)	$ (237,984)	$ (314,061)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.72)	$ (0.47)	$ (5.17)	$ (5.82)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	51,151	54,241	45,994	53,971

(1) The Company adopted Financial Accounting Standards Board Accounting Standards Update No. 2014-09 effective January 1, 2017, with full retrospective application to January 1, 2015. Results for periods prior to January 1, 2017 have been revised accordingly.

(2) Expenses include the following amounts of non-cash stock-based compensation expense:

Research and development	$ 5,605	$ 8,545	$ 13,826	$ 23,532
Selling, general and administrative	7,314	16,471	20,238	43,393

TESARO, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)

	December 31, 2016 (as revised)(1)	September 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 521,265
Accounts receivable	6,195	27,680
Inventories	14,700	50,527
Other current assets	10,515	22,257
Total current assets	817,287	621,729
Intangible assets, net	12,877	43,155
Property and equipment, net	6,640	9,877
Restricted cash	1,694	2,521
Other assets	3,795	8,436
Total assets	$ 842,293	$ 685,718

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,236	$ 5,984
Accrued expenses	68,700	123,076
Deferred revenue, current	95	95
Other current liabilities	2,978	2,287
Total current liabilities	77,009	131,442
Convertible notes, net	131,775	140,362
Deferred revenue, non-current	305	235
Other non-current liabilities	5,086	6,318
Total liabilities	214,175	278,357
Total stockholders' equity	628,118	407,361
Total liabilities and stockholders' equity	$ 842,293	$ 685,718

(1) The Company adopted Financial Accounting Standards Board Accounting Standards Update No. 2014-09 effective January 1, 2017, with full retrospective application to January 1, 2015. Results for periods prior to January 1, 2017 have been revised accordingly.

Source: TESARO, Inc.