May 9, 2017

TESARO Announces First-Quarter 2017 Operating Results

- **ZEJULA™ approved by U.S. FDA for the maintenance treatment of women with recurrent ovarian cancer, regardless of BRCA or biomarker status; commercial launch underway**
- **ZEJULA added to the NCCN Clinical Practice Guidelines in Oncology**
- **Expanded development program for niraparib in ovarian, lung and breast cancers to begin 2H 2017**
- **VARUBY® approved in Europe and launches to begin late 2Q 2017**
- **VARUBI® IV NDA re-submitted to FDA; approval anticipated late 2Q 2017**
- **TSR-042 clinical program now open to enroll patients with MSI-H endometrial cancer**
- **TSR-022 (anti-TIM-3) combination trial with TSR-042 expected to initiate mid-2017**

WALTHAM, Mass., May 09, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for first-quarter 2017 and provided an update on the Company's commercial products and development programs.

"The recent FDA approval and U.S. launch of ZEJULA represents a significant advancement for patients with recurrent ovarian cancer and marked a key milestone for the Company," said Lonnie Moulder, CEO of TESARO. "TESARO is committed to supporting people bravely facing cancer, and we are very gratified by the early positive feedback we have received from physicians and patients as they begin to utilize ZEJULA. The unprecedented results of the NOVA trial support our view of ZEJULA as the foundation of a broad franchise opportunity with potential applications across a variety of tumor types, as both a monotherapy and in combination, and we will be advancing multiple new clinical trials of niraparib in metastatic ovarian, breast and lung cancers. Following the recent approval of VARUBY by the European Commission, we are preparing to globalize our mission and bring this important product to patients in Europe beginning in June. Our immuno-oncology programs continue to rapidly advance, and we look forward to reporting initial data from our trials this year."

Recent Business Highlights

- The U.S. launch of ZEJULA is off to a strong start, with approximately 500 prescriptions written since approval. TESARO launched ZEJULA in late April, following U.S. Food and Drug Administration (FDA) approval for use as a maintenance treatment of women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response (CR or PR) to platinum-based chemotherapy. ZEJULA is the first PARP inhibitor to be approved by the FDA that does not require patient selection with a biomarker test.
- The National Comprehensive Cancer Network (NCCN) recently added ZEJULA to the NCCN Clinical Practice Guidelines in Oncology Ovarian Cancer version 1.2017—April 12, 2017—as maintenance therapy for patients with platinum-sensitive disease who are in partial or complete response after completion of two or more lines of platinum-based therapy.
- A substantial expansion of the niraparib clinical development program is underway to include multiple Phase 2 and Phase 3 combination trials of niraparib plus an anti-PD-1 antibody or AVASTIN® (bevacizumab) in patients with ovarian cancer, non-small cell lung cancer (NSCLC), advanced squamous non-small cell lung cancer, and triple negative breast cancer.
- Enrollment continues in the Phase 3 PRIMA trial of niraparib for patients with first-line ovarian cancer, the TOPACIO trial of niraparib plus KEYTRUDA® in patients with platinum-resistant ovarian cancer or with triple negative breast cancer, and in the QUADRA trial of niraparib for the treatment of patients with ovarian cancer who have received three or more prior lines of chemotherapy.
- Secondary endpoint results presented in March at the Society of Gynecologic Oncology Annual Meeting on Women's Cancer from the Phase 3 ENGOT-OV16/NOVA trial demonstrated the positive and durable treatment effect of niraparib in a broad population of patients with ovarian cancer, regardless of germline BRCA mutation status.
- VARUBY (oral formulation) was approved by the European Commission for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults, and commercial launches in Europe are planned to begin in June on a country-by-country basis.
- The VARUBI IV NDA was resubmitted to the FDA to enable potential approval during the second quarter.
- Following identification of a fixed dose and patient-centric administration schedule for the anti-PD-1 antibody, TSR-042, a registrational development program is open to enroll patients with metastatic MSI-H endometrial cancer. This study is designed to support a request for accelerated approval and Biologics License Application (BLA) submission to the FDA.
- Enrollment continues in the dose escalation phase of a study of TESARO's anti-TIM-3 antibody, TSR-022, and a

study of TSR-022 plus TSR-042, TESARO's anti-PD-1 antibody, will initiate by mid-year.
- An Investigational New Drug (IND) application for TSR-033, an anti-LAG-3 antibody, was submitted to the FDA, with a Phase 1 trial planned to begin in mid-2017.

First Quarter 2017 Financial Results

TESARO reported net product revenue of $2.1 million for the first quarter of 2017, compared to $0.3 million for the first quarter of 2016, consisting of sales of VARUBI to our specialty pharmacy and specialty distributor customers.

Research and development expenses increased to $66.1 million for the first quarter of 2017, compared to $52.7 million for the first quarter of 2016, driven primarily by higher costs related to the ongoing trials of niraparib, TSR-042 and TSR-022, advancement of our earlier-stage immuno-oncology portfolio, and increased headcount.

Selling, general and administrative expenses increased to $69.3 million for the first quarter of 2017, compared to $30.1 million for the first quarter of 2016, primarily due to activities in support of the launches of VARUBI/VARUBY and ZEJULA in the U.S. and Europe, increased headcount, and higher professional service fees.

Operating expenses as described above include total non-cash, stock-based compensation expense of $18.4 million for the first quarter of 2017, compared to $9.5 million for the first quarter of 2016.

Net loss totaled $136.7 million, or ($2.55) per share, for the first quarter of 2017, compared to a net loss of $91.0 million, or ($2.22) per share, for the first quarter of 2016.

In line with the Company's previous guidance, TESARO's cash and cash equivalents balance declined by approximately $114 million during the first quarter. As of March 31, 2017, TESARO had approximately $672 million in cash and cash equivalents and approximately 53.8 million outstanding shares of common stock.

Corporate Objectives

TESARO anticipates achieving the following key objectives:

VARUBI / VARUBY (rolapitant):

- Launch VARUBI IV into the U.S. market in mid-2017, pending FDA approval; and
- Launch VARUBY oral in Europe on a country-by-country basis beginning in June.

ZEJULA (niraparib):

- Continue to execute on the ongoing U.S. launch of ZEJULA and on pre-launch preparations in support of a European launch by year-end 2017, pending European Commission approval;
- Report initial data from the TOPACIO trial in patients with platinum-resistant, recurrent ovarian cancer at TESARO's ASCO investor event;
- Report QUADRA data in 2H 2017;
- Continue to enroll the Phase 3 PRIMA trial throughout 2017;
- Begin to initiate expanded ovarian, breast and lung cancer development program in 2017; and
- Update AVANOVA data in 2H 2017.

Immuno-Oncology Portfolio:

- Enroll patients with MSI-H metastatic endometrial cancer in the ongoing trial of TSR-042, with the intent of submitting the results and a request to FDA for accelerated approval;
- Identify the first clinical candidate within the MD Anderson collaboration in Q2 2017;
- Identify a dose and schedule for TSR-022 by mid-2017 and for TSR-022 plus an anti-PD-1 mAb in 2H 2017;
- Initiate a Phase 1 trial of TSR-033 in mid-2017; and
- Initiate pre-IND-enabling studies for a bi-specific antibody lead clinical candidate targeting PD-1/LAG-3 in 2H 2017.

Today's Conference Call and Webcast
TESARO will host a conference call to discuss the Company's first 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.

ZEJULA (niraparib) Select Important Safety Information
Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) was reported in patients treated with ZEJULA in all clinical studies. Discontinue ZEJULA if MDS/AML is confirmed.

Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients treated with ZEJULA. Do not start ZEJULA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time.

Hypertension and hypertensive crisis have been reported in patients treated with ZEJULA. Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for six months after receiving the final dose. Because of the potential for serious adverse reactions in breastfed infants from ZEJULA, advise a lactating woman not to breastfeed during treatment with ZEJULA and for one month after receiving the final dose.

In clinical studies, the most common adverse reactions included: thrombocytopenia, anemia, neutropenia, nausea, constipation, vomiting, abdominal pain/distension, mucositis/stomatitis, diarrhea, fatigue/asthenia, decreased appetite, headache, insomnia, nasopharyngitis, dyspnea, rash and hypertension.

Please see full Prescribing Information for additional Safety Information at www.zejula.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.

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 launches of ZEJULA and VARUBY in Europe, the expected approval of the rolapitant IV NDA and the timing thereof, the design and expected timing of our various planned niraparib, planned TSR-042, TSR-033, TSR-022, combination studies, and other ongoing 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, 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, including with respect to the ultimate approval and indication for niraparib in Europe, 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 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.

TESARO, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2016	**2017**
	(as revised)(1)	
Revenues:		
Product revenue, net	$ 276	$ 2,139

License, collaboration and other revenues	24	934
Total revenues	300	3,073
Expenses:		
Cost of sales - product	79	444
Cost of sales - intangible asset amortization	464	490
Research and development (2)	52,709	66,122
Selling, general and administrative (2)	30,149	69,262
Acquired in-process research and development	4,000	-
Total expenses	87,401	136,318
Loss from operations	(87,101)	(133,245)
Interest income (expense), net	(3,879)	(3,426)
Loss before income taxes	(90,980)	(136,671)
Provision for income taxes	-	54
Net loss	$ (90,980)	$ (136,725)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.22)	$ (2.55)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	40,966	53,685

(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	$ 3,743	$ 7,125
Selling, general and administrative	5,718	11,276

TESARO, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2016 (as revised)(1)	March 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 672,239
Accounts receivable	6,195	6,061
Inventories	14,700	15,643
Other current assets	10,515	13,625
Total current assets	817,287	707,568
Intangible assets, net	12,877	37,387
Property and equipment, net	6,640	8,618
Restricted cash	1,694	2,316
Other assets	3,795	5,116
Total assets	$ 842,293	$ 761,005
Liabilities and stockholders' equity		
Current liabilities:		

Accounts payable	$	5,236	$	10,343
Accrued expenses		68,700		93,765
Deferred revenue, current		95		95
Other current liabilities		2,978		3,264
Total current liabilities		77,009		107,467
Convertible notes, net		131,775		134,532
Deferred revenue, non-current		305		282
Other non-current liabilities		5,086		5,516
Total liabilities		214,175		247,797
Total stockholders' equity		628,118		513,208
Total liabilities and stockholders' equity	$	842,293	$	761,005

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Investor/Media Contact:
Jennifer Davis
Vice President, Corporate Affairs & Investor Relations
+1.781.325.1116 or jdavis@tesarobio.com