August 8, 2017

TESARO Announces Second-Quarter 2017 Operating Results

- **ZEJULA is the most prescribed PARP inhibitor in U.S.; Q2 net sales totaled $26 million in first quarter of availability**
- **Recently opened European niraparib EAP has enrolled 200 patients**
- **VARUBY oral launch now underway in Europe**
- **Dose-escalation of TSR-022 (anti-TIM-3) completed and combination trial with TSR-042 (anti-PD-1) initiated**
- **Regulatory strategy defined with FDA for TSR-042 in MSI-high cancers and registration study ongoing**
- **License agreement signed with Takeda in July for niraparib development and commercialization in Japan and certain other countries with a $100 million upfront payment and up to $240 million in milestones**

WALTHAM, Mass., Aug. 08, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for second-quarter 2017 and provided an update on the Company's commercial products and development programs.

"The U.S. launch of ZEJULA, the first and only PARP inhibitor to be approved for the maintenance treatment of women with recurrent ovarian cancer, regardless of BRCA mutation or biomarker status, is off to an excellent start, and we are gratified by the positive feedback that we have received from patients and prescribers," said Lonnie Moulder, CEO of TESARO. "Following its introduction in late April, ZEJULA quickly became the most frequently prescribed PARP inhibitor in the U.S. The MAA for ZEJULA is under review in Europe, and we are pleased that interest in our expanded access program (EAP) has been high, as we anticipate the European launch of ZEJULA by year end. We continue to globalize our mission with the recently announced Takeda licensing agreement for ZEJULA in Japan, and the launches of VARUBY oral in several EU countries. We are advancing the registration program for TSR-042, our anti-PD-1 antibody, and have initiated a combination clinical study of our anti-TIM-3 antibody, TSR-022, plus TSR-042. We are also pleased with the progress of our earlier stage immuno-oncology antibody and small molecule programs and the potential for this pipeline to establish TESARO as a leading player in the field."

Recent Business Highlights

- TESARO launched ZEJULA™ in the U.S. in April 2017, following U.S. Food and Drug Administration (FDA) approval 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 (CR or PR) to platinum-based chemotherapy. ZEJULA is the most prescribed PARP inhibitor in the U.S., with more than 1,500 new patients treated in the second quarter and prescriptions written by over 1,000 physicians since launch.
- Pre-launch preparations continue in support of a European launch of ZEJULA by year-end 2017, pending European Commission approval, and the niraparib expanded access program (EAP) has enrolled more than 200 patients across nine European countries.
- VARUBY® (oral formulation) was approved by the European Commission in April and has been launched in Germany, the U.K., Denmark, Finland and Austria. Preparations are ongoing in support of launches in additional European countries.
- VARUBI® (oral formulation) was the most prescribed oral NK-1 receptor antagonist in the U.S. for the second quarter of 2017. The NDA re-submission for the intravenous (IV) formulation of rolapitant is under review by the FDA, with a Prescription Drug User Fee Act (PDUFA) action date of October 25, 2017.
- 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.
- In July, TESARO and Takeda Pharmaceutical Company Limited announced an exclusive licensing agreement for the commercialization and clinical development of niraparib in Japan and certain other countries.
- Enrollment continues in the TOPACIO trial of niraparib plus KEYTRUDA® (pembrolizumab) in patients with platinum resistant ovarian cancer or with triple negative breast cancer, and in the AVANOVA trial of niraparib plus bevacizumab in patients with recurrent ovarian cancer. Data from the TOPACIO and AVANOVA trials are expected to be presented during the European Society for Medical Oncology (ESMO) Congress in September.
- The registration strategy for TSR-042 (anti-PD-1) has been finalized with the FDA for patients with metastatic microsatellite instability-high (MSI-H) cancers. Additional data from the Phase 1 study of TSR-042 are planned for presentation during ESMO.
- Dose-escalation of TSR-022 (anti-TIM-3) as a monotherapy is complete and a combination study of TSR-022 with TSR-042 is ongoing.

- In August, the Phase 1 dose-escalation trial for TSR-033 (anti-LAG-3) was initiated.
- IND-enabling studies are underway for bi-specific antibody candidate targeting PD-1/LAG-3.

Second Quarter 2017 Financial Results

TESARO reported net product revenue of $28.8 million for the second quarter of 2017, which included ZEJULA sales of $25.9 million and VARUBI/VARUBY sales of $2.9 million. This compares to net product revenue of $1.2 million for the second quarter of 2016.

Cost of sales totaled $6.6 million for the second quarter of 2017 and included $3.6 million associated with product revenue for the second quarter of 2017 and $3.0 million related to amortization of milestones recorded upon FDA approval of niraparib and first commercial sales of VARUBI/VARUBY in the U.S. and Europe. Cost of sales totaled $0.7 million for the second quarter of 2016.

Research and development expenses increased to $71.4 million for the second quarter of 2017, compared to $50.1 million for the second quarter of 2016, driven primarily by increased headcount, expansion of the TSR-042 and TSR-022 programs, and advancement of our earlier-stage immuno-oncology portfolio.

Selling, general and administrative expenses increased to $93.0 million for the second quarter of 2017, compared to $36.2 million for the second quarter of 2016, primarily due to activities in support of the launches of ZEJULA and VARUBI/VARUBY in the U.S. and Europe, increased headcount, and higher professional service fees.

Acquired in-process research and development expenses totaled $7.0 million for the second quarter of 2017 and included milestone payments related to our immuno-oncology portfolio, compared to $4.0 million for the second quarter of 2016, which also related to a development milestone achieved within our immuno-oncology programs.

Operating expenses as described above include total non-cash, stock-based compensation expense of $23.5 million for the second quarter of 2017, compared to $11.7 million for the second quarter of 2016.

Net loss totaled $152.1 million, or ($2.82) per share, for the second quarter of 2017, compared to a net loss of $59.2 million, or ($1.29) per share, for the second quarter of 2016.

As of June 30, 2017, TESARO had approximately $508 million in cash and cash equivalents and approximately 54.2 million outstanding shares of common stock. This cash and cash equivalents balance does not include the $100 million up-front payment received during the third quarter as part of the Takeda license agreement.

Corporate Objectives

TESARO anticipates achieving the following key objectives:

VARUBI / VARUBY (rolapitant):

- Launch VARUBI IV in the U.S. in Q4 2017, pending FDA approval; and
- Continue to execute on the VARUBY oral launch in Europe.

ZEJULA (niraparib):

- 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;
- Continue to enroll the Phase 3 PRIMA trial throughout 2017; and
- Begin to initiate expanded ovarian, breast and lung cancer development programs in 2017.

Immuno-Oncology Portfolio:

- Continue to enroll patients with MSI-H cancer in the registration trial of TSR-042, with the intent of supporting accelerated FDA approval;
- Continue enrollment in the TSR-022 plus TSR-042 combination cohort through 2017;
- Continue to enroll the Phase 1 trial of TSR-033;
- Advance IND-enabling studies for bi-specific antibody lead clinical candidate targeting PD-1/LAG-3, in 2H 2017; and
- Identify the first clinical candidate within the MD Anderson collaboration in Q3 2017.

Today's Conference Call and Webcast
TESARO will host a conference call to discuss the Company's second 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 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 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 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, 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 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 March 31, 2017.

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

	Three Months Ended June 30,	Six Months Ended June 30,

	2016 (as revised)(1)	2017	2016 (as revised)(1)	2017
Revenues:				
Product revenue, net:				
ZEJULA™	$ -	$ 25,945	$ -	$ 25,945
VARUBI®/VARUBY®	1,242	2,884	1,518	5,023
Total product revenue, net	1,242	28,829	1,518	30,968
License, collaboration and other revenues	34,568	635	34,592	1,569
Total revenues	35,810	29,464	36,110	32,537
Expenses:				
Cost of sales - product	234	3,620	313	4,064
Cost of sales - intangible asset amortization	463	2,979	927	3,469
Research and development (2)	50,138	71,400	102,847	137,522
Selling, general and administrative (2)	36,218	92,979	66,367	162,241
Acquired in-process research and development	4,000	7,000	8,000	7,000
Total expenses	91,053	177,978	178,454	314,296
Loss from operations	(55,243)	(148,514)	(142,344)	(281,759)
Interest income (expense), net	(3,911)	(3,467)	(7,790)	(6,893)
Loss before income taxes	(59,154)	(151,981)	(150,134)	(288,652)
Provision for income taxes	-	78	-	132
Net loss	$ (59,154)	$ (152,059)	$ (150,134)	$ (288,784)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.29)	$ (2.82)	$ (3.46)	$ (5.36)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	45,808	53,982	43,387	53,834

(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	$ 4,479	$ 7,862	$ 8,222	$ 14,987
Selling, general and administrative	7,206	15,646	12,924	26,922

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

	December 31, 2016 (as revised)(1)	June 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 785,877	$ 507,941
Accounts receivable	6,195	23,149
Inventories	14,700	28,285
Other current assets	10,515	23,045

Total current assets	817,287	582,420
Intangible assets, net	12,877	44,408
Property and equipment, net	6,640	9,958
Restricted cash	1,694	2,522
Other assets	3,795	6,087
Total assets	$ 842,293	$ 645,395
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,236	$ 45
Accrued expenses	68,700	99,589
Deferred revenue, current	95	95
Other current liabilities	2,978	2,701
Total current liabilities	77,009	102,430
Convertible notes, net	131,775	137,447
Deferred revenue, non-current	305	258
Other non-current liabilities	5,086	5,346
Total liabilities	214,175	245,481
Total stockholders' equity	628,118	399,914
Total liabilities and stockholders' equity	$ 842,293	$ 645,395

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