February 28, 2017

# TESARO Announces Fourth-Quarter 2016 Operating Results

- **Niraparib NDA under review by FDA; pre-launch preparations for planned commercial launch well underway**
- **Expanded access program (EAP) for niraparib open in U.S.; European EAP expected to open 1H 2017**
- **Positive opinion rendered for VARUBY® by the European Medicine Agency's CHMP; European launch planned for 2Q 2017**
- **International headquarters and European operations established to cover 17 target countries**
- **Registration program for niraparib in lung cancer to be finalized in 1H 2017**
- **TSR-042 (anti-PD-1 antibody) registration program to initiate in 2Q 2017**
- **Cash and cash equivalents totaled approximately $786 million as of December 31, 2016**

WALTHAM, Mass., Feb. 28, 2017 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today reported operating results for fourth-quarter 2016 and provided an update on the Company's development programs.

"2017 is poised to be an eventful year for TESARO as we prepare for four product launches across the United States and Europe," said Lonnie Moulder, CEO of TESARO. "2016 was an important year for the Company, highlighted by the landmark NOVA trial results for niraparib, which were published in the *New England Journal of Medicine* and presented in a presidential session at the European Society of Medical Oncology annual meeting. We intend to build upon these successes in 2017 with the planned launch of niraparib in the U.S. during the first half of this year and in Europe by year end. Looking beyond ovarian and breast cancer, we aim to finalize our registration program for niraparib in lung cancer in the first half of this year. Lastly, we are excited about the progress in our immuno-oncology pipeline, and expect to initiate a registrational program for TSR-042 in the coming months."

### Recent Business Highlights

- The U.S. launch of VARUBI® continues, with sequential unit volume growth for the fourth quarter of 2016. For the month of December, VARUBI achieved greater than 40% market share in the oral NK-1 market in the U.S., which represents the market-leading position in the category.
- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) rendered a positive opinion for the marketing authorization application (MAA) for VARUBY® for the prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults.
- In January, TESARO received a Complete Response Letter regarding the rolapitant IV New Drug Application (NDA) for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy. TESARO expects to be able to address the questions from the U.S. Food and Drug Administration (FDA) and resubmit the NDA to enable approval in the first half of 2017.
- The NDA for niraparib was accepted for review by the FDA for patients with recurrent ovarian cancer following response to platinum-based chemotherapy. The FDA granted priority review for the niraparib NDA and established a Prescription Drug User Fee Act (PDUFA) goal date of June 30, 2017.
- An expanded access program (EAP) for niraparib opened in the U.S. in January, through which niraparib is being made available for eligible women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following a complete or partial response to platinum-based chemotherapy. An EAP for niraparib is planned to open in Europe in the first half of 2017, and will be initiated on a country-by-country basis.
- Enrollment continues in the Phase 3 PRIMA trial of niraparib for patients with first-line ovarian cancer, the Phase 3 BRAVO trial for patients with germline BRCA-mutated, metastatic 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.
- Based upon the anti-tumor activity observed in Phase 1 of the TOPACIO trial of niraparib plus KEYTRUDA® (pembrolizumab) in patients with ovarian cancer or with triple negative breast cancer, the trial has expanded to Phase 2 and is enrolling patients. Initial data are expected at an upcoming medical meeting.
- Following the presentation of data at ASCO in 2016, the Phase 2 portion of the AVANOVA trial of niraparib plus bevacizumab in patients with ovarian cancer continues to enroll, and updated data are expected in 2H 2017.
- Dose escalation and identification of a fixed dose and schedule was completed for the Phase 1 trial of TSR-042, an anti-PD-1 antibody candidate, and a registration trial is planned to begin in 1H 2017.
- Enrollment continues in the Phase 1 dose escalation study of TSR-022, an anti-TIM-3 antibody candidate.
- A lead PD-1/LAG-3 bi-specific antibody candidate was identified.

**Fourth Quarter 2016 Financial Results**

TESARO reported revenue of $4.2 million for the fourth quarter of 2016, compared to revenue of $0.2 million for the fourth quarter of 2015. Net product revenue for the fourth quarter of 2016 totaled $2.5 million and included sales of VARUBI from specialty pharmacy customers to patients and from specialty distributors to providers that were made during the fourth quarter. License, collaboration and other revenue for the fourth quarter of 2016 totaled $1.8 million and included amortization of up-front payments and shipments of clinical materials under our license agreements with Hengrui and Janssen.

Research and development expenses increased to $71.5 million for the fourth quarter of 2016, compared to $42.9 million for the fourth quarter of 2015, driven primarily by higher costs related to the ongoing registration trials of niraparib, manufacturing and other research and development costs related to niraparib, advancement of our immuno-oncology portfolio, and increased headcount.

Selling, general and administrative expenses increased to $54.5 million for the fourth quarter of 2016, compared to $27.9 million for the fourth quarter of 2015, primarily due to commercial activities in support of the launch of VARUBI, pre-launch activities related to niraparib, expansion of the European commercial organization, increased headcount and higher professional service fees.

Acquired in-process research and development expenses totaled $9.0 million for the fourth quarter of 2016 and included milestone payments related to niraparib, compared to $1.0 million for the fourth quarter of 2015, which included a milestone payment related to our immuno-oncology portfolio.

Operating expenses, as described above, include total non-cash, stock-based compensation expense of $14.4 million for the fourth quarter of 2016, compared to $8.4 million for the fourth quarter of 2015.

Net loss totaled $136.9 million, or ($2.60) per share, for the fourth quarter of 2016, compared to a net loss of $75.8 million, or ($1.89) per share, for the fourth quarter of 2015.

As of December 31, 2016, TESARO had approximately $785.9 million in cash and cash equivalents and approximately 53.6 million outstanding shares of common stock. Excluding the proceeds from the November 2016 financing, our cash and cash equivalents balance declined $95.7 million in the fourth quarter.

**Full-Year 2016 Financial Results**

TESARO reported revenue of $44.8 million for 2016, compared to revenue of $0.3 million for 2015. Net product revenue for 2016 totaled $6.9 million and included sales of VARUBI from specialty pharmacy customers to patients and from specialty distributors to providers through December 31, 2016. License, collaboration and other revenue for 2016 totaled $37.9 million and included amortization of up-front payments and shipments of clinical materials under our license agreements with Hengrui and Janssen.

Research and development expenses increased to $235.1 million for 2016, compared to $155.4 million for 2015, driven primarily by three ongoing registration trials of niraparib, increased headcount, and advancement of our immuno-oncology portfolio.

Selling, general and administrative expenses increased to $158.6 million for 2016, compared to $78.7 million for 2015, primarily due to increased headcount, commercial and pre-launch activities in support of VARUBI and niraparib, expansion of the European commercial organization, and higher professional service fees.

Acquired in-process research and development expenses totaled $18.9 million for 2016 and included milestone payments related to niraparib and our immuno-oncology portfolio, compared to $2.0 million for 2015, which included milestone payments related to our immuno-oncology portfolio.

Operating expenses, as described above, include total non-cash, stock-based compensation expense of $48.5 million for 2016, compared to $25.9 million for 2015.

Net loss totaled $387.5 million, or ($8.13) per share, for 2016, compared to a net loss of $251.4 million, or ($6.38) per share, for 2015.

In anticipation of four product launches in 2017, TESARO will continue to invest in pre-launch inventory manufacturing and development of supply chain capabilities and capacity, in addition to making milestone payments for regulatory submissions. TESARO expects its cash and cash equivalents balance to decline by approximately $110 to $120 million on

average, per quarter, during the first half of 2017, excluding one-time regulatory milestones of $35 million expected to be paid at the time of the first commercial sale of VARUBY oral in Europe and approval of niraparib in the U.S.

**2017 Corporate Objectives**

TESARO anticipates achieving the following key objectives:

VARUBI (rolapitant):

- Launch VARUBI IV into the U.S. market in mid-2017, pending FDA approval; and
- Launch VARUBY oral in Europe in 2Q 2017, pending EMA approval.

Niraparib:

- Continue commercial preparations in support of the launches of niraparib in the U.S. in 1H 2017 and Europe by year-end 2017, pending regulatory approvals;
- Report initial data from TOPACIO trial at upcoming medical meeting;
- Report QUADRA data in 2H 2017;
- Report Phase 3 BRAVO data in 2H 2017;
- Continue to enroll the Phase 3 PRIMA trial throughout 2017;
- Finalize a potential lung cancer registration strategy in 1H 2017 and initiate the development program;
- Update AVANOVA data in 2H 2017; and
- Describe the potential registration strategy for niraparib plus TSR-042 in ovarian and other cancers in 2H 2017.

Immuno-Oncology Portfolio:

- Identify a dose and schedule for TSR-022 (anti-TIM-3 antibody) by mid-2017;
- Submit an IND for TSR-033 (anti-LAG-3 antibody) in 2Q 2017;
- Finalize the TSR-042 registration strategy and initiate a registration program in 1H 2017;
- Identify the first clinical candidate within the MD Anderson collaboration in 1H 2017; and
- Initiate a Phase 1 clinical trial of TSR-022 in combination with an anti-PD-1 antibody in mid-2017.

**Today's Conference Call and Webcast**

TESARO will host a conference call to discuss the Company's fourth quarter operating results and provide an update on the Company's development programs and the VARUBI® launch 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 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 launches of niraparib and VARUBI IV in the U.S., the expected timing of our planned commercial launches of niraparib and oral rolapitant in Europe, the expected launch of our EAP in Europe, the expected timing of finalizing our registration program for niraparib in lung cancer, the expected timing of initiation of our TSR-042 registration program, the expected approval of the rolapitant IV NDA, the expected timing of data from our TOPACIO, AVANOVA and other ongoing clinical trials, our expected cash utilization during the first half of 2017, and our expectation to achieve our various key 2017 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 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, uncertainties regarding certain expenditures, risks related to manufacturing and supply, 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, 2015, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | 2015 | 2016 | 2015 | 2016 |
| Revenues: | | | | |
| Product revenue, net | $ - | $ 2,469 | $ - | $ 6,877 |
| License, collaboration and other revenues | 230 | 1,756 | 317 | 37,946 |
| Total revenues | 230 | 4,225 | 317 | 44,823 |
| Expenses: | | | | |
| Cost of sales - product | - | 518 | - | 1,256 |
| Cost of sales - intangible asset amortization | 268 | 464 | 268 | 1,855 |
| Research and development (1) | 42,852 | 71,514 | 155,390 | 235,144 |
| Selling, general and administrative (1) | 27,910 | 54,526 | 78,701 | 158,578 |
| Acquired in-process research and development | 1,000 | 9,000 | 2,000 | 18,940 |
| Total expenses | 72,030 | 136,022 | 236,359 | 415,773 |
| Loss from operations | (71,800) | (131,797) | (236,042) | (370,950) |
| Interest income (expense), net | (3,959) | (3,670) | (15,366) | (15,047) |
| Loss before income taxes | (75,759) | (135,467) | (251,408) | (385,997) |
| Provision for income taxes | - | 1,475 | - | 1,475 |
| Net loss | $ (75,759) | $ (136,942) | $ (251,408) | $(387,472) |
| Net loss per share applicable to common stockholders - basic and diluted | $ (1.89) | $ (2.60) | $ (6.38) | $ (8.13) |
| Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted | 40,151 | 52,589 | 39,387 | 47,652 |

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

| | | | | |
|---|---|---|---|---|
| Research and development | $ 3,274 | $ 5,957 | $ 11,082 | $ 19,783 |
| Selling, general and administrative | 5,130 | 8,434 | 14,832 | 28,672 |

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

| | December 31, 2015 | December 31, 2016 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |

| | | |
|---|---|---|
| Cash and cash equivalents | $ 230,146 | $ 785,877 |
| Accounts receivable | 679 | 5,343 |
| Inventories | 1,106 | 14,700 |
| Other current assets | 4,560 | 8,919 |
| Total current assets | 236,491 | 814,839 |
| | | |
| Intangible assets, net | 14,732 | 12,877 |
| Property and equipment, net | 2,779 | 6,640 |
| Restricted cash | 500 | 1,694 |
| Other assets | 779 | 3,795 |
| Total assets | $ 255,281 | $ 839,845 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 8,019 | $ 5,236 |
| Accrued expenses | 36,628 | 68,271 |
| Deferred revenue, current | 500 | 288 |
| Other current liabilities | 1,534 | 2,978 |
| Total current liabilities | 46,681 | 76,773 |
| | | |
| Convertible notes, net | 121,325 | 131,775 |
| Deferred revenue and customer deposit, non-current | 288 | 15,000 |
| Other non-current liabilities | 113 | 5,086 |
| Total liabilities | 168,407 | 228,634 |
| | | |
| Total stockholders' equity | 86,874 | 611,211 |
| Total liabilities and stockholders' equity | $ 255,281 | $ 839,845 |


Investor/Media Contact:

Jennifer Davis
+1.781.325.1116 or jdavis@tesarobio.com

Kate Rausch
+1.781.257.2505 or krausch@tesarobio.com