



March 10, 2016

## **Threshold Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Year-End 2015 Financial Results**

*-- Rights to Evofosfamide and Relevant Merck KGaA, Darmstadt, Germany Technology Returned to Threshold; Merck KGaA, Darmstadt, Germany Retains Certain Royalty and Milestone Payments Dependent Upon Successful Development and Commercialization of Evofosfamide --*

*-- Additional Analyses of Data from the MAESTRO Study in Pancreatic Cancer Demonstrate Meaningful Improvement in Median Overall Survival and Other Secondary Efficacy Endpoints for Japanese Patients --*

SOUTH SAN FRANCISCO, Calif., March 10, 2016 (GLOBE NEWSWIRE) -- Threshold Pharmaceuticals, Inc. (Nasdaq:THLD), a clinical-stage biopharmaceutical company developing novel therapies for cancer, today reported financial results for the fourth quarter and year ended December 31, 2015 and provided an update on the Company's corporate and clinical development activities.

"A key focus for Threshold has been to analyze all of the evofosfamide clinical data to determine whether there might be a path forward in patients with pancreatic cancer as well as other cancer indications," said Barry Selick, Ph.D., Chief Executive Officer of Threshold. "We have finalized an agreement with Merck KGaA, Darmstadt, Germany to license back all rights to evofosfamide and, based upon a detailed ongoing analysis of the data from the Phase 3 MAESTRO trial, we have seen a meaningful improvement in median overall survival and other secondary efficacy endpoints in the 116 Japanese patients with pancreatic cancer who were enrolled in that trial."

### **Corporate Highlights**

On March 10, 2016, the Company terminated the global license and co-development agreement (License Agreement) with Merck KGaA, Darmstadt, Germany, originally entered into February 2, 2012 for evofosfamide, Threshold's investigational hypoxia-activated prodrug of a cytotoxic DNA-alkylating agent. Under the terms of the Termination Agreement, all rights to evofosfamide under the original agreement were returned to Threshold, as well as all rights to Merck KGaA, Darmstadt, Germany technology developed under the License Agreement. The Termination Agreement provides tiered royalties on sales and milestone payments to Merck KGaA, Darmstadt, Germany contingent upon the future successful development and commercialization of evofosfamide.

In January 2016 at the American Society of Clinical Oncology 2016 Gastrointestinal Cancers Symposium (ASCO GI), Merck KGaA, Darmstadt, Germany's analysis of the results from the Phase 3 MAESTRO trial were presented. While the primary efficacy endpoint of overall survival narrowly missed statistical significance, secondary efficacy endpoints of progression-free survival and confirmed overall response rates demonstrated significant improvements for patients treated with gemcitabine plus evofosfamide (the "treatment arm") compared to gemcitabine plus placebo (the "control arm"). No new safety findings were identified in the MAESTRO study and the safety profile was consistent with that previously reported in other studies of evofosfamide plus gemcitabine.

As previously reported, a meaningful improvement in overall survival was reported for the subgroup of 123 Asian patients enrolled at Japanese and South Korean sites in which the risk of death was reduced by 42 percent for patients on the treatment arm compared to patients on the control arm with an associated hazard ratio of 0.58 (95% CI: 0.36 - 0.93).

Of particular note, based upon Merck KGaA, Darmstadt, Germany's MAESTRO data, the Company reported that the 116 patients from Japan from the treatment arm had a median overall survival of 13.6 months compared to 9.1 months for those patients in the control arm. The patients from Japan also had significant improvements in progression free survival, objective response rates, and reductions in the pancreatic cancer biomarker, CA19-9.

The Company is conducting additional analyses of data from the MAESTRO study in pancreatic cancer and intends to discuss potential registration pathways with health regulatory authorities. While the Company has ongoing clinical development collaborations investigating evofosfamide in patients with pancreatic neuroendocrine tumors (pNET), recurrent glioblastoma (GBM) and hepatocellular carcinoma (HCC), it has suspended the development of evofosfamide in various other tumor types.

"The detailed analysis of the MASTRO data combined with our previous Phase 2 experience strongly suggests that

evofosfamide plus gemcitabine is an active regimen in patients with pancreatic cancer, most notably in the Japanese patients, and we look forward to being able to share our future plans based on these data," added Dr. Selick. "Beyond evofosfamide, we continue to make progress with our two Phase 2 proof-of-concept trials of tarloxotinib, our hypoxia-activated EGFR tyrosine kinase inhibitor, and plan to share preliminary results of those clinical trials in mid-2016."

#### **Fourth Quarter and Year End 2015 Financial Results**

- | As of December 31, 2015 and 2014, Threshold had \$48.7 million and \$58.6 million in cash, cash equivalents and marketable securities, respectively. The net decrease of \$9.9 million in cash, cash equivalents and marketable securities during 2015 is primarily due to the Company's operating cash requirements for 2015, partially offset by the \$28.1 million in net proceeds from our public offering in February 2015 and \$0.7 million in cash proceeds from the exercise of stock options and purchase rights related to our stock-based equity incentive plans.
- | Revenue for the fourth quarter and year ended December 31, 2015 was \$65.9 million and \$76.9 million, respectively, compared to \$3.7 million and \$14.7 million for the same periods in 2014, respectively. Revenue for the years ended December 31, 2015 and December 31, 2014, related to the amortization of the aggregate of \$110 million in upfront and milestone payments earned in 2013 and 2012 from the Company's collaboration with Merck KGaA, Darmstadt, Germany. The revenue from the upfront payment and milestone payments earned under the agreement was previously being amortized over the relevant performance period, rather than being immediately recognized when the upfront payment and milestone were earned or received. As a result of Merck KGaA, Darmstadt, Germany's and our decision to cease further joint development of evofosfamide in December 2015, we immediately recognized \$65.9 million of the remaining deferred revenue into revenue during the quarter ending December 31, 2015. Also as a result of the termination of the agreement, we are no longer eligible to receive any further milestone payments from Merck KGaA, Darmstadt, Germany.
- | Research and development expenses were \$11.4 million for the fourth quarter ended December 31, 2015, compared to \$8.6 million for the same period in 2014. The increase in research and development expenses, net of reimbursement for Merck KGaA, Darmstadt, Germany's 70% share of total development expenses for evofosfamide, was due primarily to a \$1.2 million increase in employee related expenses, including a \$0.3 million increase in non-cash stock-based compensation expense and a \$1.6 million increase in clinical development expenses and consulting expenses. Research and development expenses were \$40.3 million for 2015, compared to \$35.8 million in 2014. The increase in research and development expenses, net of reimbursement for Merck KGaA, Darmstadt, Germany's 70% share of total development expenses for evofosfamide, was due primarily to a \$2.1 million increase in clinical development expenses and an increase of \$2.7 million in employee related expenses, including a \$1.0 million increase in non-cash stock-based compensation expense. Partially offsetting these increases was a \$0.4 million decrease in consulting expenses.
- | General and administrative expenses were \$2.2 million for the fourth quarter of 2015 versus \$2.6 million for the fourth quarter of 2014. The decrease in general and administrative expenses was due primarily to a \$0.2 million decrease in consulting expenses and a \$0.2 million decrease in employee related expenses. General and administrative expenses were \$9.7 million for 2015 versus \$10.1 million for 2014. The decrease in general and administrative expenses was due primarily to a \$0.4 million decrease in consulting expenses.
- | Non-cash stock-based compensation expense included in total operating expenses was \$2.0 million for the fourth quarter of 2015 versus \$1.6 million for the fourth quarter of 2014. Non-cash stock-based compensation expense included in total operating expenses was \$6.8 million for 2015 versus \$5.5 million for 2014. The increase in stock-based compensation expense was due to the amortization of a greater number of options with higher fair values.
- | Net income for the fourth quarter of 2015 was \$69.7 million compared to a net loss of \$6.0 million for the fourth quarter of 2014. Included in the net income for the fourth quarter of 2015 was an operating income of \$52.3 million and non-cash income of \$17.4 million compared to an operating loss of \$7.6 million and non-cash income of \$1.6 million in the fourth quarter of 2014. The net income for 2015 was \$43.8 million compared to a net loss of \$21.6 million in 2014. Included in the net income for 2015 was an operating income of \$26.9 million and non-cash income of \$16.8 million compared to an operating loss of \$31.3 million and non-cash income of \$9.3 million in 2014. The non-cash income or expense is related to changes in the fair value of the Company's outstanding and exercised warrants that was classified as other income (expense).

#### **About Evofosfamide**

Evofosfamide (previously known as TH-302) is an investigational hypoxia-activated prodrug of a bis-alkylating agent that is preferentially activated under severe hypoxic tumor conditions, a feature of many solid tumors. Areas of low oxygen levels (hypoxia) in solid tumors are due to insufficient blood vessel supply. Similarly, the bone marrow of patients with hematological malignancies has also been shown, in some cases, to be severely hypoxic. On December 6, 2015, the Company announced the outcomes of two Phase 3 studies (MAESTRO and TH-CR-406/SARC021) of evofosfamide stating that neither study met its primary endpoint. The related news release can be accessed on the Company's website.

#### **About Tarloxotinib Bromide**

Tarloxotinib bromide (the proposed International Nonproprietary Name, previously known as TH-4000), or "tarloxotinib", is a prodrug designed to selectively release a covalent (irreversible) EGFR tyrosine kinase inhibitor under severe hypoxia, a feature of many solid tumors. Accordingly, tarloxotinib has the potential to effectively shut down aberrant EGFR signaling in

a tumor-selective manner, thus potentially avoiding or reducing the systemic side effects associated with currently available EGFR tyrosine kinase inhibitors. Tarloxotinib is currently being evaluated in two Phase 2 proof-of-concept trials: one for the treatment of patients with mutant EGFR-positive, T790M-negative advanced non-small cell lung cancer progressing on an EGFR tyrosine kinase inhibitor, and the other for patients with recurrent or metastatic squamous cell carcinomas of the head and neck or skin. Threshold licensed exclusive worldwide rights to tarloxotinib from the University of Auckland, New Zealand, in September 2014.

### About Threshold Pharmaceuticals

Threshold is a clinical-stage biopharmaceutical company focused on the discovery and development of drugs and diagnostic agents targeting tumor hypoxia, the low oxygen condition found in microenvironments of most solid tumors as well as the bone marrows of some hematologic malignancies. This approach offers broad potential to treat a variety of cancers. By selectively targeting tumor cells, we are building a pipeline of drugs that hold promise to be more effective and less toxic to healthy tissues than conventional anticancer drugs. For additional information, please visit the Company's website.

### Forward-Looking Statements

Except for statements of historical fact, the statements in this press release are forward-looking statements, including all statements regarding anticipated development activities and clinical development outlook related to company-sponsored clinical trials for evofosfamide and tarloxotinib, including establishing collaborations for our product candidates, the planned analyses of evofosfamide and tarloxotinib clinical trials, and the timing thereof; the expected efficient execution of, and the anticipated timing of protocol-specified events and the availability of the results of the primary efficacy analyses from the evofosfamide and tarloxotinib clinical trials; the potential submission of marketing applications for evofosfamide; the timing of the Phase 2 proof-of-concept study of tarloxotinib; potential development opportunities for evofosfamide, including the potential for Threshold's evofosfamide Phase 3 clinical trial to support registration for the treatment of patients with advanced pancreatic cancer, and other cancers; and the therapeutic potential of tarloxotinib. These statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to: the ability of Threshold to establish collaborations for our product candidates or otherwise raise substantial additional capital; Threshold's dependence on the transfer of development activities from Merck KGaA, Darmstadt, Germany, including its dependence on decisions by Merck KGaA, Darmstadt, Germany regarding the amount and timing of resource expenditures for the transfer of evofosfamide development activities and the risk of potential disagreements with Merck KGaA, Darmstadt, Germany, regarding the time and expense required to transfer clinical trials and analyze data; the uncertainty of clinical success and regulatory approval; the risk that later analysis may not confirm the results of earlier analysis; the risks that the design of, or data collected from, the Phase 3 clinical trials of evofosfamide may be inadequate to demonstrate safety and efficacy, or otherwise may be insufficient to support any marketing authorization submissions and/or regulatory approvals, and that despite the potential benefits of the SPA agreements with the FDA, significant uncertainty remains regarding the regulatory approval process for evofosfamide and that evofosfamide may not receive any marketing approvals in a timely manner or at all; issues arising in the regulatory process and the results of such clinical trials (including product safety issues and efficacy results); dependence of Threshold on single source suppliers, including the risk that these single source suppliers may be unable to meet clinical supply demands for evofosfamide and/or tarloxotinib which could significantly delay the development of evofosfamide and/or tarloxotinib; Threshold's ability to enroll or complete tarloxotinib clinical trials, including the ability of Threshold to complete the ongoing clinical trials in the expected timeframe or at all; the risks that Threshold's evaluation of tarloxotinib is at an early stage and it is possible that tarloxotinib may not be found to be safe or effective in the Phase 2 proof-of-concept study of tarloxotinib or in any other studies of tarloxotinib that Threshold may conduct, and that Threshold may otherwise fail to realize the anticipated benefits of its licensing of this product candidate; and Threshold's need for and the availability of resources to develop evofosfamide and tarloxotinib and to support Threshold's operations. Further information regarding these and other risks is included under the heading "Risk Factors" in Threshold's Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission on March 10, 2016 and is available from the SEC's website ([www.sec.gov](http://www.sec.gov)) and on our website ([www.thresholdpharm.com](http://www.thresholdpharm.com)) under the heading "Investors". We undertake no duty to update any forward-looking statement made in this news release.

**THRESHOLD PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)  
(Unaudited)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2015	2014	2015	2014
Revenue	\$ 65,874	\$ 3,681	\$ 76,915	\$ 14,722
Operating expenses				

Research and development	11,369	8,609	40,271	35,832
General and administrative	2,248	2,623	9,716	10,141
<b>Total Operating Expenses</b>	<u>13,617</u>	<u>11,232</u>	<u>49,987</u>	<u>45,973</u>
<b>Income (loss) from operations</b>	52,257	(7,551)	26,928	(31,251)
Interest income (expense), net	26	24	125	121
Other income (expense) (1)	17,430	1,563	16,769	9,344
<b>Income (loss) before provision for taxes</b>	<u>69,713</u>	<u>(5,964)</u>	<u>43,822</u>	<u>(21,786)</u>
Provision for income taxes	-	-	-	(202)
<b>Net income (loss)</b>	<u>\$ 69,713</u>	<u>\$ (5,964)</u>	<u>\$ 43,822</u>	<u>\$ (21,584)</u>

**Net income (loss) per common share**

<b>Basic</b>	<u>\$ 0.98</u>	<u>\$ (0.09)</u>	<u>\$ 0.62</u>	<u>\$ (0.36)</u>
<b>Diluted</b>	<u>\$ 0.86</u>	<u>\$ (0.12)</u>	<u>\$ 0.54</u>	<u>\$ (0.49)</u>

**Weighted-average shares used in per common share calculation:**

<b>Basic</b>	<u>71,457</u>	<u>62,814</u>	<u>70,242</u>	<u>60,335</u>
<b>Diluted</b>	<u>73,686</u>	<u>63,544</u>	<u>73,483</u>	<u>63,386</u>

(1) Noncash income (expense) related to change in the fair value of the Company's outstanding and exercised warrants, classified as other income (expense).

**THRESHOLD PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	December 31, 2015	December 31, 2014
	(unaudited)	(1)
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 48,680	\$ 58,600
Collaboration Receivable	1,891	7,248
Prepaid expenses and other current assets	2,599	832
Property and equipment, net	333	557
Other assets	166	1,159
Total assets	<u>\$ 53,669</u>	<u>\$ 68,396</u>
<b>Liabilities and stockholders' equity</b>		
Total current liabilities (2)	\$ 10,828	\$ 25,974
Deferred Revenue	-	62,194
Long-term liabilities (3)	1,995	4,204
Stockholders' equity (deficit)	40,846	(23,976)
Total liabilities and stockholders' equity (deficit)	<u>\$ 53,669</u>	<u>\$ 68,396</u>

(1) Derived from audited financial statements

(2) Amount includes current portion of deferred revenue of \$0 million and \$14.7 million as of December 31, 2015 and 2014, respectively.

(3) Includes as of December 31, 2015 and 2014, \$1.9 million and \$4.0 million of warrant liability, respectively.

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