



May 5, 2016

Threshold Pharmaceuticals Reports First Quarter Financial Results

SOUTH SAN FRANCISCO, Calif., May 05, 2016 (GLOBE NEWSWIRE) -- Threshold Pharmaceuticals, Inc. (Nasdaq:THLD), a clinical-stage biopharmaceutical company developing novel therapies for cancer, today reported financial results for the first quarter ended March 31, 2016 and provided an update on the Company's corporate and clinical development activities.

"We remain focused on establishing a potential regulatory path forward for evofosfamide as well as a possible strategic partnering initiative, and we are making progress on both of these fronts," said Barry Selick, Ph.D., Chief Executive Officer of Threshold. "I am also pleased with the appointment of Stew Kroll as Chief Operating Officer who most capably leads the strategy, design and execution of our clinical development programs."

Recent Highlights

Evofosfamide - The Company's lead product candidate is an investigational hypoxia-activated prodrug that is designed to be activated under tumor hypoxic conditions, a hallmark of many cancers. Additional analysis of the MASTRO Phase 3 data combined with 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.

- | Conducted additional analyses of evofosfamide data in pancreatic cancer; the Company intends to discuss potential registration pathways with health regulatory authorities; and
- | Continued ongoing clinical development collaborations investigating evofosfamide in patients with pancreatic neuroendocrine tumors (pNET), recurrent glioblastoma (GBM) and hepatocellular carcinoma (HCC).

Tarloxotinib - Beyond the Company's evofosfamide program, the clinical development team is focused on tarloxotinib, a hypoxia-activated epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), which is designed to selectively release an irreversible EGFR-TKI in hypoxic tumors.

- | Continued to enroll patients in two proof-of-concept Phase 2 clinical trials in patients with advanced non-small cell lung cancer (NSCLC) as well as metastatic head and neck squamous cell carcinoma; the Company plans to share preliminary results from both trials in mid-2016.

First Quarter 2016 Financial Results

- | Cash, cash equivalents and marketable securities totaled \$38.0 million at March 31, 2016 compared to \$48.7 million at December 31, 2015; the net decrease was a result of operating cash requirements for the quarter ended March 31, 2016, including the payment of \$2.3 million of accrued severance benefits related to the previously announced workforce reduction in December of 2015. With the previously announced decision to cease joint development of evofosfamide under the Company's former collaboration with Merck KGaA and the workforce reduction, the Company expects its quarterly operating cash requirements to decrease for the remainder of fiscal year 2016 compared to the first quarter ended March 31, 2016.
- | No revenue was recognized in the first quarter ended March 31, 2016 compared to \$3.7 million for the same period of 2015. Revenue for the quarter ended March 31, 2015 related to the amortization of the aggregate of \$110 million in upfront and milestone payments received from the Company's former collaboration with Merck KGaA, Darmstadt, Germany. The revenue from the upfront payment and milestone payments received under the agreement were previously being amortized over the relevant performance period, rather than being immediately recognized when the upfront payment and milestones were earned or received. As a result of Merck KGaA, Darmstadt, Germany's and the Company's decision to cease further joint development of evofosfamide in December 2015, the Company immediately recognized all of the remaining deferred revenue into revenue during the quarter ending December 31, 2015. Also as a result of the termination of the agreement, the Company is no longer eligible to receive any further milestone payments from Merck KGaA, Darmstadt, Germany.
- | Research and development expenses were \$6.0 million for the first quarter ended March 31, 2016, compared to \$10.7 million for the same period in 2015. The decrease in research and development expenses, net of reimbursement for Merck KGaA, Darmstadt, Germany's 70 percent share of total eligible collaboration expenses for evofosfamide, was due primarily to a \$3.1 million decrease in employee related expenses, including a \$0.5 million decrease in non-cash stock-based compensation expense and a \$1.6 million decrease in clinical development

expenses and consulting expenses. The Company expects research and development expenses to continue to decline in 2016 as result of the decision to cease further joint development of evofosfamide under the Company's former collaboration with Merck KGaA and the workforce reduction.

- | General and administrative expenses were \$2.2 million for the first quarter of 2016 compared to \$2.6 million for the same period in 2015. 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.
- | Non-cash stock-based compensation expense included in total operating expenses was \$0.8 million for the first quarter of 2016 compared to \$1.4 million for the same period in 2015. The decrease in stock-based compensation expense was due to the amortization of a smaller number of options with lower fair values.
- | Net loss for the first quarter of 2016 was \$7.9 million compared to \$11.2 million for the same period in 2015. Included in the net loss for the first quarter of 2016 was an operating loss of \$8.3 million and non-cash income of \$0.4 million compared to an operating loss of \$9.6 million and non-cash expense of \$1.5 million for the first quarter of 2015. 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.

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 varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval; 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 and even if we are successful in raising the additional capital necessary, Threshold's ability to advance the development of its product candidates; 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; the amount and timing of licensing fees, milestone payments and royalty payments that we are obligated to pay; 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 was filed with the Securities and Exchange Commission on March 10, 2016 and is available from the SEC's website (www.sec.gov) and on our website (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	
	March 31,	
	2016	2015
Revenue	\$ —	\$ 3,681
Operating expenses		
Research and development	6,005	10,680
General and administrative	2,249	2,616
Total Operating Expenses	8,254	13,296
Loss from operations	(8,254)	(9,615)
Interest income (expense), net	32	33
Other Income (expense), net (1)	370	(1,572)
Net loss	(7,852)	(11,154)
Net loss per share:		
Basic	\$ (0.11)	\$ (0.17)
Diluted	\$ (0.11)	\$ (0.17)
Weighted-average shares used in net loss per share calculations:		
Basic	71,488	66,732
Diluted	71,488	66,732

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

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

	March 31, 2016	December 31, 2015 (1)
	(unaudited)	
Assets		
Cash, cash equivalents and marketable securities	\$ 37,966	\$ 48,680
Collaboration Receivable	777	1,891
Prepaid expenses and other current assets	1,880	2,599
Property and equipment, net	261	333
Other assets	166	166
Total assets	\$ 41,050	\$ 53,669
Liabilities and stockholders' equity		
Total current liabilities	\$ 5,575	\$ 10,828
Long-term liabilities (2)	1,603	1,995
Stockholders' equity (deficit)	33,872	40,846
Total liabilities and stockholders' equity (deficit)	\$ 41,050	\$ 53,669

(1) Derived from audited financial statements

(2) Includes as of March 31, 2016 and December 31 2015, \$1.5 million and \$1.9 million of warrant liability, respectively.

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Source: Threshold Pharmaceuticals, Inc.

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