

### Threshold Pharmaceuticals Reports Second Quarter Financial Results

-- Presented additional subset data at ASCO from Phase 3 MAESTRO trial of evofosfamide in pancreatic cancer; meaningful improvement in overall survival in patients from Asia --

SOUTH SAN FRANCISCO, Calif., Aug. 01, 2016 (GLOBE NEWSWIRE) -- Threshold Pharmaceuticals, Inc. (Nasdaq:THLD), a clinical-stage biopharmaceutical company developing novel therapies for cancer, today reported financial results for the second quarter ended June 30, 2016 and provided an update on the Company's corporate and clinical development activities.

"Encouraged by the MAESTRO data presented recently at ASCO that demonstrated meaningful improvement in overall survival in the subgroup of patients from Japan and South Korea, we are pursuing a registration strategy for Japan," said Barry Selick, Ph.D., Chief Executive Officer of Threshold. "We have also been encouraged by the translational data evaluating the role of hypoxia in mediating treatment resistance to cancer immunotherapy conducted by collaborators at the MD Anderson Cancer Center and to initiating a clinical trial evaluating evofosfamide in combination with checkpoint blockade."

#### **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 data analyses from the MAESTRO Phase 3 trial, which were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting recently, reported on the subgroup of 123 Asian patients enrolled at Japanese and South Korean sites in which the risk of death was reduced by 48 percent for patients on the treatment arm compared to patients on the control arm with an associated stratified hazard ratio of 0.52 (95% CI: 0.32 0.85);
- The Company is evaluating the feasibility of submitting a New Drug Application (NDA) for registration with the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan based on the results seen in the Japanese subpopulation;
- Clinical development collaborations investigating evofosfamide in patients with pancreatic neuroendocrine tumors (pNET), recurrent glioblastoma (GBM) and hepatocellular carcinoma (HCC) remain ongoing; and
- A recent presentation by one of the Company's collaborators from the MD Anderson Cancer Center highlighted the promise of evofosfamide in combination with "checkpoint antibodies" to improve the efficacy of this class of potent anti-cancer therapies. A clinical trial evaluating evofosfamide plus ipilimumab to treat a variety of solid tumors is planned.

**Tarloxotinib** - Beyond the evofosfamide program, the Company is pursuing the Phase 2 proof of concept studies with 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.

Investigations continue in two proof-of-concept, Phase 2 clinical trials in patients with advanced non-small cell lung cancer (NSCLC) and patients with metastatic squamous cell carcinoma of the head and neck and skin; the designs of both trials necessitate a minimum response rate for study continuation. When the specified target numbers of patients have been assessed, the Company plans to report the preliminary results; this is estimated to occur in the third quarter of 2016.

#### Second Quarter 2016 Financial Results

- Cash, cash equivalents and marketable securities totaled \$33.6 million at June 30, 2016 compared to \$38.0 million at March 31, 2016; the net decrease of \$4.4 million was a result of operating cash requirements for the quarter ended June 30, 2016. 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 continues to expect its operating cash requirements to be lower for the second half of fiscal year 2016 compared to the first half of 2016.
- No revenue was recognized in the second quarter ended June 30, 2016 compared to \$3.7 million for the same period of 2015. Revenue for the quarter ended June 30, 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 \$4.0 million for the second quarter ended June 30, 2016, compared to \$10.1 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 \$3.6 million decrease in employee related expenses, including a \$0.9 million decrease in non-cash stock-based compensation expense and a \$2.5 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 \$1.9 million for the second quarter ended June 30, 2016 compared to \$2.5 million for the same period in 2015. The decrease in general and administrative expenses was due primarily to a \$0.5 million decrease in employee related expenses and a \$0.1 million decrease in consulting expenses.
- Non-cash stock-based compensation expense included in total operating expenses was \$0.8 million for the second quarter of 2016 compared to \$1.9 million for 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 second quarter of 2016 was \$6.9 million compared to \$8.3 million for the same period in 2015. Included in the net loss for the second quarter of 2016 was an operating loss of \$5.9 million and non-cash expense of \$1.0 million compared to an operating loss of \$8.9 million and non-cash income of \$0.6 million for the second 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 outlooks related to company-sponsored clinical trials for evofosfamide and tarloxotinib, including 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 in Japan in view that the FDA recently considered the MAESTRO data insufficient to support registration in the U.S., the varying interpretations of the MAESTRO data which could prevent registration; and even if

approved, the reduced commercial potential of evofosfamide, if only approved in Japan; the timing of the Phase 2 proof of concept study of tarloxotinib, its therapeutic potential; and Threshold's ability to advance development of evofosfamide and tarloxotinib without establishing new collaborations for our product candidates and otherwise raise substantial additional capital. 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, 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.

Three Months Ended

Six Months Ended

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

Three Months Ended June 30.			Six Months Ended June 30,				
2016		2015		2016		2015	
\$	-	\$	3,680	\$	-	\$	7,361
	4,016		10,141		10,021		20,821
	1,892		2,480		4,141		5,096
	5,908		12,621		14,162		25,917
	(5,908)		(8,941)		(14,162)		(18,556)
	40		39		72		72
	(996)		596		(626)		(976)
\$	(6,864)	\$	(8,306)	\$	(14,716)	\$	(19,460)
\$	(0.10)	\$	(0.12)	\$	(0.21)	\$	(0.28)
\$	(0.10)	\$	(0.12)	\$	(0.21)	\$	(0.28)
	71,511		71,334		71,500		69,046
	\$	\$ - 4,016 1,892 5,908 (5,908) 40 (996) \$ (6,864) \$ (0.10)	\$ - \$  4,016 1,892 5,908 (5,908)  40 (996) \$ (6,864) \$  \$ (0.10) \$ \$	June 30,       2016     2015       \$ - \$ 3,680       4,016 10,141 1,892 2,480 5,908 12,621       (5,908) (8,941)       40 39 (996) 596 596       \$ (6,864) (8,306)       \$ (0.10) (0.12) (0.12)	June 30,       2016     2015       \$ - \$ 3,680 \$       4,016 10,141 1,892 2,480 5,908 12,621       (5,908) (8,941)       40 39 (996) 596 \$ (996) 596 \$ (6,864) \$ (8,306) \$ \$       \$ (6,864) \$ (8,306) \$ \$       \$ (0.10) \$ (0.12) \$ \$ (0.12) \$ \$	June 30,     June 2016       2016     2015       \$ - \$ 3,680 \$ -       4,016 10,141 10,021 1,892 2,480 4,141 5,908 12,621 14,162       (5,908) (8,941) (14,162)       40 39 72 (996) 596 (626)	June 30,     June 30       2016     2015       \$ - \$ 3,680 \$ - \$       4,016 10,141 10,021 1,892 2,480 4,141 5,908 12,621 14,162       (5,908) (8,941) (14,162)       40 39 72 (996) 596 (626) \$ (626) \$ (6864) \$ (8,306) \$ (14,716) \$ \$       \$ (0.10) \$ (0.12) \$ (0.21) \$ \$ (0.21) \$ \$ (0.21) \$ \$

Diluted	71,511	72,815	71,500	69,046

(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)

Assets	une 30, <u>2016</u> naudited)	December 31, <u>2015</u> (1)		
Cash, cash equivalents and				
marketable securities	\$ 33,591	\$	48,680	
Collaboration Receivable	921		1,891	
Prepaid expenses and other current assets	1,294		2,599	
Property and equipment, net	208		333	
Other assets	166		166	
Total assets	\$ 36,180	\$	53,669	
Liabilities and stockholders' equity				
Total current liabilities	\$ 5,789	\$	10,828	
Long-term liabilities (2)	2,577		1,995	
Stockholders' equity (deficit)	27,814		40,846	
Total liabilities and stockholders' equity (deficit)	\$ 36,180	\$	53,669	

- (1) Derived from audited financial statements
- (2) Includes as of June 30, 2016 and December 31, 2015, \$2.5 million and \$1.9 million of warrant liability, respectively.

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