



Threshold Pharmaceuticals Presents Interim Data From a Phase 1/2 Clinical Trial of TH-302 at Sarcoma Meeting

REDWOOD CITY, Calif., Nov 6, 2009 (GlobeNewswire via COMTEX News Network) -- Threshold Pharmaceuticals, Inc. (Nasdaq:THLD) today announced clinical trial results related to Threshold's clinical stage hypoxia-activated prodrug, TH-302. The results were presented at the 15th Annual Connective Tissue Oncology Society (CTOS) Meeting taking place in Miami Beach, Florida from November 5 to 7, 2009.

Today's presentation focused on a clinical trial, the 403 trial, which is investigating TH-302 in combination with doxorubicin in patients with soft tissue sarcoma who have not received prior doxorubicin. Twelve patients have had at least one evaluable post-treatment tumor assessment, including 3 (25%) with a partial response (PR) as measured by RECIST (Response Evaluation Criteria In Solid Tumors). Two of the PRs are confirmed, including one patient who has remained on study for 33 weeks. One of the PRs was unconfirmed due to progression at the subsequent assessment. Five of the 12 patients continue to receive TH-302 after receiving TH-302 for 3 to 13 three-week cycles. Seven (58%) patients achieved stable disease while 2 (17%) had progressive disease. Additional patients are being enrolled to better define the extent of the tumor response activity.

"For sarcoma patients, median survival is about one year regardless of stage of disease, so we are definitely in need of new agents to help these patients. We believe that TH-302 may 'complement' doxorubicin, the standard of care in sarcoma, and treat that portion of the tumor that typically does not respond to this traditional chemotherapy agent," said John Curd, M.D., Threshold's chief medical officer. "This clinical trial has thus far established that TH-302 can be safely combined with full doses of doxorubicin, and the preliminary data suggests that TH-302 may add to the activity and durability of doxorubicin."

TH-302 continues to be tolerated and there have been no new unexpected adverse events in the 14 patients assessed for safety. Nausea was the most commonly reported adverse event and was reported in 8 (57%) patients. After observing significant, but not dose limiting toxicity at a TH-302 dose of 240 mg/m², prophylactic growth factor support was initiated. Two dose limiting toxicities, grade 3 cellulitis with grade 4 neutropenia and grade 4 thrombocytopenia, were observed in 2 of 4 patients treated at a TH-302 dose of 340 mg/m². The maximum tolerated dose (MTD) was then established at 300 mg/m². Skin toxicity is common with 9 of 14 (64%) patients having at least one skin adverse event. All were grade 1 or 2 with the exception of the one patient with grade 3 cellulitis. Eight (57%) patients had a mucosal adverse event; all were grade 1 or 2.

A copy of the poster may be obtained by calling the Company.

About The Clinical Trial

The 403 trial is a Phase 1/2, multicenter, dose escalation trial to determine the safety, efficacy and pharmacokinetics of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma. The trial was initiated in September 2008. The trial will enroll up to 36 patients including 12 patients treated at the MTD as part of the dose expansion component of the trial. TH-302 is administered intravenously on days 1 and 8 of a 21 day cycle. Doxorubicin is dosed according to its package insert (75 mg/m² on day 1 of the 21 day cycle). The Phase 1/2 clinical trial has completed the dose escalation component, reached the MTD and is currently enrolling patients in the dose expansion cohort.

The Company has two additional ongoing clinical trials of TH-302. The Company is in the process of completing a Phase 1/2 clinical trial of TH-302 in combination with various chemotherapies in patients with advanced solid tumors. The Company is also continuing a Phase 1/2 clinical trial of TH-302 as monotherapy in patients with advanced solid tumors.

About Threshold Pharmaceuticals

Threshold is a biotechnology company focused on the discovery and development of drugs targeting Tumor Hypoxia, the low oxygen condition found in microenvironments of most solid tumors. This approach offers broad potential to treat most solid tumors. 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 website (www.thresholdpharm.com).

Forward-Looking Statements

Except for statements of historical fact, the statements in this press release are forward-looking statements, including statements regarding TH-302's uses and potential benefits and clinical trial results and plans. 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, Threshold's ability to enroll and complete its current and anticipated clinical trials, the time and expense required to conduct such clinical trials and analyze data, the possibility that results from these trials will not be confirmed, potential adverse side effects, issues arising in the regulatory or manufacturing process and the results of such clinical trials (including product safety issues and efficacy results). Further information regarding these and other risks is included under the heading "Risk Factors" in Threshold's Quarterly Report on Form 10-Q, which was filed with the Securities Exchange Commission on November 5, 2009 and is available from the SEC's website (www.sec.gov) and on our website (www.thresholdpharm.com) under the heading "Investors." Threshold does not intend to update any forward-looking statement made in this news release.

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