



## Threshold Pharmaceuticals Provides Clinical Development Update at J.P. Morgan Healthcare Conference

REDWOOD CITY, Calif., Jan 12, 2010 (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 are being presented at the 28th Annual J.P. Morgan Healthcare Conference taking place in San Francisco from January 11 to 14, 2010.

The Company has three ongoing phase 1/2 clinical trials of TH-302. The "401 trial" is a trial of TH-302 as monotherapy in patients with advanced solid tumors. The "402 trial" is a three arm trial of TH-302 in combination with gemcitabine or docetaxel or pemetrexed in patients with advanced solid tumors. The "403 trial" is a trial of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma. To date, TH-302 has been administered to more than 200 cancer patients.

The 402 trial is expected to enroll 120 patients in total and includes dose escalation and dose expansion portions of the trial. In 81 patients assessed to date, 23 patients (28%) had a RECIST criteria partial response (PR), 38 patients (47%) achieved stable disease (SD) and 20 patients (25%) had progressive disease (PD). The partial response included both confirmed and unconfirmed partial responses. These results are consistent with what the Company presented at the Congress of the European CanCer Organisation (ECCO) in September 2009. Importantly, with TH-302 plus gemcitabine in 17 patients with first-line pancreatic cancer, 16 patients (94%) achieved SD or better including 5 PRs and 8 continuing on the trial. With TH-302 plus docetaxel or pemetrexed in 10 patients with non-small cell lung cancer (NSCLC), 9 patients (90%) achieved SD or better including 5 PRs and 5 with progression-free survival over 5 months.

In general, hematologic toxicity in the 402 trial was higher than might be expected if chemotherapy was administered by itself. Some of the dose limiting toxicities reported with each of the combination chemotherapies have been hematologic. Skin and mucosal toxicities have been TH-302 dose dependent with a trend for increased frequency and greater severity at higher doses. Dose expansions were initiated at TH-302 doses of between 340 and 400 mg/m<sup>2</sup>. The addition of TH-302 to standard chemotherapies does not appear to enhance the toxicity in other body systems.

"We are extremely pleased with the activity of TH-302, especially when combined with full dose chemotherapy," said Barry Selick, Ph.D., Threshold's chief executive officer. "Within the next few weeks we will be finalizing which cancer indication will be the target of our first controlled Phase 2 trial of TH-302, which we expect will be either front-line pancreatic cancer or relapsed/refractory non-small cell lung cancer. We believe that the Phase 1/2 results are sufficiently promising for each of these indications to warrant continued development in either one alone, or both."

The 403 trial is expected to enroll up to 36 patients with soft tissue sarcoma. In 20 patients assessed to date, 5 patients (25%) had a PR and 12 patients (60%) achieved SD while 3 patients (15%) had PD. TH-302 continues to be tolerated and there have been no new serious unexpected adverse events in patients assessed for safety. Nausea was the most commonly reported adverse event. After observing significant, but not dose limiting toxicity at a TH-302 dose of 240 mg/m<sup>2</sup>, prophylactic growth factor support was initiated. The maximum tolerated dose (MTD) has been established at 300 mg/m<sup>2</sup>. Skin toxicity and mucosal toxicities are common with 50% of patients having at least one skin adverse event and 55% of patients at least one mucosal adverse event. All were grade 1 or 2 with the exception of the one patient with grade 3 cellulitis and one patient with grade 3 vaginitis.

The 401 trial is expected to enroll up to 126 patients. The primary objectives of the 401 trial are to determine the MTD and dose-limiting toxicities of TH-302 in patients with advanced solid tumors and to make an assessment of the efficacy of TH-302 in patients with metastatic melanoma, small cell lung cancer (SCLC) and NSCLC. In 19 patients with relapsed or refractory metastatic melanoma, 11 patients (58%) achieved SD or better including 3 PRs. In 7 patients with relapsed or refractory SCLC, 4 patients (57%) achieved SD or better including 2 PRs.

Starting on the afternoon of Thursday, January 14, a live webcast of the Company's presentation will be available under the Webcasts section of the Company's website. A replay of the presentation will be archived on the site for 90 days.

### 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](http://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](http://www.sec.gov)) and on our website ([www.thresholdpharm.com](http://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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