



Threshold Pharmaceuticals Provides Clinical Trial Update From a Complete Phase 1/2 Clinical Trial of TH-302 in Combination With Chemotherapy

REDWOOD CITY, Calif., Sep 21, 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 Congress of the European CanCer Organisation (ECCO) and 34th Congress of the European Society for Medical Oncology (ESMO) taking place in Berlin, Germany from September 20 to 24, 2009.

The clinical trial is a Phase 1/2, three arm, multicenter, dose escalation and dose expansion trial to determine the safety, efficacy and pharmacokinetics of TH-302 in combination with gemcitabine or docetaxel or pemetrexed in patients with advanced solid tumors. The trial was initiated in August 2008 and is expected to enroll 120 patients in total. This is being followed by a dose expansion phase at the recommended Phase 2 dose in four specific indications. The dose expansion phase of the trial will enroll 48 patients. The results of the dose escalation phase of the trial were reported today by Dr. Mitesh Borad from the Mayo Clinic in Scottsdale, Arizona.

To date, 45 patients in the dose-escalation phase have been assessed for response. Of the 45 patients assessed, 12 patients (27%) had a RECIST criteria partial response (PR), 22 patients (49%) achieved stable disease (SD) and 11 patients (24%) had progressive disease. The partial response included both confirmed and unconfirmed partial responses. In a confirmed partial response, partial response was maintained through a subsequent response assessment at least 28 days later, and in an unconfirmed partial response, the partial response was reported at one assessment but was not maintained in a subsequent response assessment. When the Company last reported clinical trial results at the American Society for Clinical Oncology (ASCO) in May 2009, 30 patients in the dose-escalation phase of this clinical trial had been assessed for response via the same criteria. Of the 30 patients assessed for ASCO, 7 patients (23%) had a PR and 16 patients (53%) achieved SD.

In today's presentation, in the TH-302 plus gemcitabine arm, TH-302 is administered intravenously for 30 to 60 minutes on days 1, 8 and 15 of a 28 day cycle. Gemcitabine is dosed according to its package insert. The TH-302 maximum tolerated dose (MTD) has not been established with the dose cohort currently being expanded at 340 mg/m². Two dose limiting toxicities were reported at each of two higher TH-302 doses levels. Fifteen patients have had tumor assessments, 6 of whom had a PR in the following cancers: pancreatic (2), ovarian, esophageal, squamous non-small cell lung cancer (NSCLC) and thyroid and 7 patients with SD. Dose expansion will be initiated in patients with first-line pancreatic cancer. Of the 4 patients with first-line pancreatic cancer assessed for response, 2 achieved PRs and 2 have had SD.

In the TH-302 plus docetaxel arm, TH-302 is administered intravenously on days 1 and 8 of a 21 day cycle. Docetaxel is dosed according to its package insert. The TH-302 MTD has been established at 340 mg/m² and the dose expansion has been initiated at this dose in patients with castrate resistant prostate cancer and in patients with second-line NSCLC. Eleven patients have had tumor assessments, 2 of whom achieved PRs in NSCLC and anal cancer and 6 patients with SD.

In the TH-302 plus pemetrexed arm, TH-302 is administered intravenously on days 1 and 8 of a 21 day cycle. Pemetrexed is dosed according to its package insert. The TH-302 MTD has been established at 480 mg/m² and the dose expansion has been initiated at a TH-302 dose of 400 mg/m² in patients with second-line non-squamous NSCLC. Nineteen patients have had tumor assessments, 4 of whom achieved PRs in NSCLC (2) and transitional cell carcinoma (2) and 9 patients with SD.

Overall 8 patients with relapsed or refractory NSCLC have been treated with TH-302 in combination with either docetaxel or pemetrexed and have been assessed for response. Of the 8 patients assessed, 3 patients achieved PRs, 4 patients achieved SD and 1 patient had PD. The median time on treatment for the 8 patients has been 5.3 months.

"We are encouraged by both the safety and activity we have observed in combining TH-302 with full dose chemotherapy," said John Curd, M.D., Threshold's president and chief medical officer. "Historically, the response rates in first-line pancreatic cancer with gemcitabine and in second-line NSCLC with docetaxel or pemetrexed have been less than ten percent. While we recognize that we need to explore the efficacy in a larger group of patients with the dose expansion studies that we've recently initiated, we believe that these initial data are quite promising for both of these indications."

In general, hematologic toxicity was higher than might be expected if chemotherapy was administered by itself, but was generally well tolerated. Some of the dose limiting toxicities reported with each of the combination chemotherapies have been hematologic. Skin and mucosal toxicities were TH-302 dose dependent with a trend for increased frequency and greater severity at higher doses. The addition of TH-302 to standard chemotherapies does not appear to enhance the toxicity in other body systems.

A copy of the poster presented at ECCO/ESMO may be obtained by calling the Company.

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 as monotherapy in patients with advanced solid tumors. The Company is also continuing a Phase 1/2 clinical trial of TH-302 in combination with doxorubicin in patients with advanced soft tissue sarcoma.

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 August 6, 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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