



Threshold Presents Clinical Trial Data From a Phase 1/2 Clinical Trial of TH-302 at ASCO Gastrointestinal Conference

REDWOOD CITY, Calif., Jan 25, 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 were presented at the 2010 Gastrointestinal Cancers Symposium that took place in Orlando, Florida from January 22 to 24, 2010.

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 results of the trial discussed only those patients who were treated for gastrointestinal cancer which included but were not limited to cancers of the pancreas, colon and bile duct.

To date, of the 43 patients enrolled with gastrointestinal cancer, 38 patients have been assessed for response. Of the 38 patients assessed, 12 patients (32%) had a RECIST criteria partial response (PR), 22 patients (58%) achieved stable disease (SD) and 4 patients (10%) had progressive disease (PD). 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 or has yet to be assessed after the initial assessment in response.

In today's presentation, the majority of the patients had first-line pancreatic cancer, 18 of whom received TH-302 plus gemcitabine, 3 of whom received TH-302 plus pemetrexed and one who received TH-302 plus docetaxel. Across the 22 patients with pancreatic cancer, 20 patients were assessed for response and 19 (95%) achieved stable disease or better. For these 20 patients, the mean time on study was over 3.5 months and 9 patients continue to receive therapy on study. The TH-302 maximum tolerated dose (MTD) continues under investigation with the dose cohort currently being expanded at 340 mg/m².

"While limited in number, the results we have seen in first-line pancreatic cancer are notable as compared to historical standards," said John Curd, M.D., Threshold's president and chief medical officer. "Historically, the response rates in first-line pancreatic cancer with gemcitabine have been less than ten percent. We believe that the current safety and activity data supports an additional study of TH-302 in combination with full dose gemcitabine to determine if TH-302 adds clinical benefit to patients fighting pancreatic cancer."

In general, hematologic toxicity was more frequent and more severe in the combinations than might be expected if chemotherapy was administered by itself, but the combinations were 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 other most common adverse events are fatigue and nausea. The addition of TH-302 to standard chemotherapies does not appear to enhance the toxicity in other body systems.

About the Clinical Trial

The trial was initiated in August 2008 and is expected to enroll 120 patients in total across various solid tumors but primarily focused on pancreatic cancer and non-small cell lung cancer. 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. TH-302 is currently being investigated at a dose of 340 mg/m² in combination with full dose gemcitabine in patients with first-line pancreatic cancer. 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. TH-302 is currently being investigated at a dose of 340 mg/m² in combination with full dose docetaxel in patients with second-line NSCLC and in patients with first-line castrate-resistant prostate cancer. 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. TH-302 is currently being investigated at a dose of 400 mg/m² in combination with full dose pemetrexed in patients with second-line non-squamous NSCLC.

A copy of the poster presented at the ASCO Gastrointestinal Cancers Symposium may be obtained by calling the Company.

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 by additional data or in trials with larger numbers of patients, 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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