



## Results From TH-302 Clinical Trials Presented at International Lung Cancer Meeting

REDWOOD CITY, Calif and SCOTTSDALE, Ariz, Aug 4, 2009 (GlobeNewswire via COMTEX News Network) -- Threshold Pharmaceuticals, Inc. (Nasdaq:THLD) and the Virginia G. Piper Cancer Center at Scottsdale Healthcare today announced clinical trial results related to Threshold's clinical stage hypoxia-activated prodrug, TH-302. The results were presented at the World Conference on Lung Cancer being held July 31 to August 4, 2009, at the Moscone Convention Center in San Francisco, CA.

"TH-302 is a new, novel, small molecule that is activated when cells are under conditions that lack oxygen, which is a metabolic condition characteristic of cancer cells," said Glen Weiss, M.D., Director of Thoracic Oncology at the Virginia G. Piper Cancer Center's Scottsdale Clinical Research Institute, and a clinical investigator for the trial. "We are excited to continue investigations with TH-302 and about the potential benefit that it might confer to people living with lung cancer."

The presentation summarized results from two Phase 1 clinical trials of TH-302. Results from these trials were previously discussed at the American Society of Clinical Oncology Meeting in May 2009. The two clinical trials are both evaluating the safety and preliminary efficacy of TH-302 in patients with advanced solid tumors; one in combination with other chemotherapy agents and the other with TH-302 as monotherapy. Results from twenty-one patients with relapsed/refractory lung cancer across the two clinical trials were presented in an oral presentation entitled "TH-302: Bench to bedside with a tumor-selective hypoxia-activated prodrug for lung cancer."

Clinical trial patients are seen by Dr. Weiss at the TGen Clinical Research Service clinic in the Virginia G. Piper Cancer Center at Scottsdale Healthcare.

### Clinical Trial Results

Thirteen patients with non small cell lung cancer (NSCLC) have been enrolled in either the combination therapy or the monotherapy clinical trial. These patients had received a median of two prior systemic therapies. Tumors were assessed utilizing RECIST (Response Evaluation Criteria In Solid Tumors). Partial responses were observed in three patients, one patient receiving docetaxel and TH-302, and two patients receiving pemetrexed and TH-302. Eight of 12 (67%) evaluable patients achieved stable disease or better.

Eight patients with small cell lung cancer (SCLC) were enrolled in the clinical trial evaluating TH-302 as monotherapy. These patients had received a median of three prior systemic therapies. Partial responses were observed in two patients. As previously reported, one patient with refractory SCLC metastatic to the liver had a partial response, as judged by RECIST, at their initial response assessment. The patient had received two cycles of TH-302 and discontinued from study after treatment delay unrelated to therapy, and disease progression. In the expansion phase of the monotherapy clinical trial an additional patient with SCLC had a partial response. Six of 8 (75%) patients achieved stable disease or better.

Skin and mucosal toxicities were the most common TH-302 related toxicities with 17 of 21 (81%) patients reporting skin toxicity and 12 of 21 (57%) patients reporting mucosal toxicity. These were all grade 1 or grade 2 except for one event of grade 3 cheilitis and one event of grade 3 macular rash. The skin toxicities improved with local treatments including topicals or, in some cases, dose delay or dose reduction. Hematologic toxicity has been minimal with no grade 3/4 neutropenia or thrombocytopenia in the 13 patients on monotherapy and 50% grade 3/4 neutropenia and 25% grade 3/4 thrombocytopenia in patients receiving TH-302 in combination with chemotherapy.

Enrollment in both studies continues. Patients with relapsed/refractory SCLC or NSCLC are enrolling in the monotherapy study; NSCLC patients eligible for second-line chemotherapy are enrolling in the combination study.

### About the Virginia G. Piper Cancer Center at Scottsdale Healthcare

The Virginia G. Piper Cancer Center at Scottsdale Healthcare offers diagnosis, treatment, research and support in its facilities at the Scottsdale Healthcare Shea Medical Center, attracting patients from across Arizona and the U.S. Groundbreaking cancer research is conducted through its Scottsdale Clinical Research Institute and TGen Clinical Research Service. It is a primary clinical research site for the Translational Genomics Research Institute and the Stand Up To Cancer Pancreatic Cancer Research Dream Team. Scottsdale Healthcare is the not-for-profit parent organization of the Scottsdale Healthcare Shea Medical Center, Scottsdale Healthcare Osborn Medical Center and Scottsdale Healthcare Thompson Peak Hospital, Virginia G. Piper Cancer Center, Scottsdale Clinical Research Institute and Scottsdale Healthcare Foundation. For additional information, please visit the website ([www.shc.org](http://www.shc.org)).

## 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 Threshold's product candidates, clinical trial results and plans, and potential therapeutic uses and benefits of our product candidates. 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 May 7, 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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