June 6, 2016

Threshold Pharmaceuticals Highlights Multiple Presentations at the 2016 ASCO Annual Meeting

Presentation of additional subset data from Phase 3 MAESTRO trial of evofosfamide in pancreatic cancer demonstrates meaningful improvement in overall survival in patients from Asia; risk of death reduced by almost 50 percent

CHICAGO, June 06, 2016 (GLOBE NEWSWIRE) -- Threshold Pharmaceuticals, Inc. (NASDAQ:THLD) today announced multiple presentations on clinical trials on its hypoxia-activated prodrugs, evofosfamide and tarloxotinib at the American Society of Clinical Oncology (ASCO) Annual Meeting being held June 3 through 7, 2016 in Chicago, Ill.

Today, Threshold presented additional data from its analysis of the randomized, double-blind Phase 3 MAESTRO clinical trial of evofosfamide (TH-302) in combination with gemcitabine in previously untreated patients with metastatic or locally advanced unresectable pancreatic ductal adenocarcinoma conducted by Merck KGaA. A meaningful improvement in overall survival was reported for the subgroup of 123 Asian patients enrolled at Japanese and South Korean sites in which the risk of death was reduced by 48 percent for patients on the treatment arm compared to patients on the control arm with an associated stratified hazard ratio of 0.52 (95% CI: 0.32 - 0.85). The patients from Asia also had significant improvements in PFS, objective response rates, and reductions in the pancreatic cancer biomarker, CA19-9 (abstract 4007). As previously reported in January 2016, the primary efficacy endpoint of this study of overall survival narrowly missed statistical significance based on specified intent-to-treat analysis while showing improvements in secondary efficacy endpoints of progression-free survival (PFS) and response.

On June 4, 2016, the following posters were displayed:

Randomized, Double-Blind, Placebo-Controlled Trial of Evofosfamide and Pemetrexed in Second Line Advanced Non-Squamous Non-Small Cell Lung Cancer. Csoszi et al. (abstract 9075).

As reported in January 2016, the study was stopped early based on a futility analysis of overall survival conducted by the study Data and Safety Monitoring Board (DSMB). The study enrolled 265 patients of a planned 440 patients. The response rate with evofosfamide plus pemetrexed was 18.0 percent and significantly higher compared to 8.1 percent with placebo plus pemetrexed. The median PFS with evofosfamide plus pemetrexed was 4.5 months (95% CI: 4.0 to 6.4 months) and significantly higher compared to 2.9 (95% CI: 2.6 to 4.1) months with placebo plus pemetrexed. Hematologic toxicity was greater in the evofosfamide plus pemetrexed arm, while non-hematologic toxicity was similar across treatment arms. No new safety signals were identified.

Evofosfamide combined with gemcitabine/nab-paclitaxel in patients with previously untreated locally advanced or metastatic pancreatic adenocarcinoma (PAC): results of a phase I trial. Borad et al. (abstract 4114).

Nineteen patients were treated for a median of 6 cycles. The maximum tolerated dose of evofosfamide was established at 340 mg/m^2 in combination with 800 mg/m^2 gemcitabine and 100 mg/m^2 nab-paclitaxel. No new safety signals were identified with myelosuppression being the primary dose limiting toxicity. The best response rate was 53 percent and the confirmed response rate was 37 percent.

Two additional trials-in-progress posters were also displayed:

A Phase 2 Study of Tarloxotinib Bromide (TRLX) in Patients with Recurrant or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) or Skin (SCCS).
Rischin et al. (abstract TPS6105)

A Phase 2 Study (NCT02454842) of Tarloxotinib Bromide (TH-4000) in Patients with EGFR Mutant, T790M-Negative, Advanced NSCLC Progressing on an EGFR TKI.
Liu et al. (abstract TPS9100)

Copies of the posters may be obtained from Threshold's website, www.thresholdpharm.com, under Scientific Publications.

About Evofosfamide
Evofosfamide (previously known as TH-302) is an investigational hypoxia-activated prodrug of a bis-alkylating agent that is preferentially activated under severe hypoxic tumor conditions, a feature of many solid tumors. Areas of low oxygen levels (hypoxia) in solid tumors are due to insufficient blood vessel supply. Similarly, the bone marrow of patients with hematological malignancies has also been shown, in some cases, to be severely hypoxic. On December 6, 2015, the Company announced the outcomes of two Phase 3 studies (MAESTRO and TH-CR-406/SARC021) of evofosfamide stating that neither study met its primary endpoint.

About Tarloxotinib Bromide
Tarloxotinib bromide (the proposed International Nonproprietary Name, previously known as TH-4000), or "tarloxotinib", is a prodrug designed to selectively release a covalent (irreversible) EGFR tyrosine kinase inhibitor under severe hypoxia, a feature of many solid tumors. Accordingly, tarloxotinib has the potential to effectively shut down aberrant EGFR signaling in a tumor-selective manner, thus potentially avoiding or reducing the systemic side effects associated with currently available EGFR tyrosine kinase inhibitors. Tarloxotinib is currently being evaluated in two Phase 2 proof-of-concept trials: one for the treatment of patients with mutant EGFR-positive, T790M-negative advanced non-small cell lung cancer progressing on an EGFR tyrosine kinase inhibitor, and the other for patients with recurrent or metastatic squamous cell carcinomas of the head and neck or skin. Threshold licensed exclusive worldwide rights to tarloxotinib from the University of Auckland, New Zealand, in September 2014.

About Threshold Pharmaceuticals
Threshold is a clinical-stage biopharmaceutical company focused on the discovery and development of drugs and diagnostic agents targeting tumor hypoxia, the low oxygen condition found in microenvironments of most solid tumors as well as the bone marrows of some hematologic malignancies. This approach offers broad potential to treat a variety of cancers. 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 Company's website.

Forward-Looking Statements
Except for statements of historical fact, the statements in this press release are forward-looking statements, including statements regarding the potential therapeutic uses and benefits of its product candidates, evofosfamide and tarloxotinib, including statements related to potential clinical and regulatory paths forward for 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: the difficulty and uncertainty of pharmaceutical product development, including the time and expense required to conduct clinical trials and analyze data, and the uncertainty of clinical success and regulatory approval; issues arising in the regulatory or manufacturing process and the results of such clinical trials (including safety issues and efficacy results); the dependence of Threshold on single source suppliers for evofosfamide, including the risk that these single source suppliers may be unable to meet clinical supply demands for evofosfamide which could significantly delay the development of evofosfamide; the amount and timing of resource expenditures for the development of evofosfamide; the commencement of additional clinical trials; and Threshold's need for and the availability of resources to develop its drug candidates and to support Threshold's operations. Further information regarding these and other risks is included under the heading "Risk Factors" in Threshold's Quarterly Report on Form 10-Q, which has been filed with the Securities and Exchange Commission on May 5, 2016 and is available from the SEC's website (www.sec.gov) and on our website (www.thresholdpharm.com) under the heading "Investors". We undertake no duty to update any forward-looking statement made in this news release.

Contact

Denise Powell

denise@redhousecomms.com

510.703.9491

Primary Logo

Source: Threshold Pharmaceuticals, Inc.