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Threshold Pharmaceuticals Announces First Patient Dosed in Immunotherapy Clinical Trial of Evofosfamide and Ipilimumab

-- Phase 1 clinical trial will evaluate the effect of ipilimumab and evofosfamide (TH-302) in advanced solid tumors --

-- Company management to host "Hypoxia and Immunotherapy" conference call today at 4:15 p.m. Eastern Time --

MENLO PARK, Calif., June 13, 2017 (GLOBE NEWSWIRE) -- Threshold Pharmaceuticals, Inc. (NASDAQ:THLD) a clinical-stage biopharmaceutical company developing novel therapies for cancer, today announced that the University of Texas MD Anderson Cancer Center has dosed the first patient in a Phase 1 immunotherapy clinical trial investigating ipilimumab and evofosfamide for the treatment of patients with metastatic or locally advanced prostate cancer, metastatic pancreatic cancer, melanoma or human papillomavirus (HPV) negative squamous cell carcinoma of head and neck for which standard therapy does not offer the potential for increased survival.

"We believe that adding evofosfamide to certain immunotherapies has the potential to render some of the most therapeutically resistant cancers more sensitive to the immunotherapy and we are excited to have dosed the first patient in this study," said Tillman Pearce, M.D., Chief Medical Officer at Threshold Pharmaceuticals. "Thanks to preclinical research conducted by Dr. Curran at MD Anderson Cancer Center, it is well-understood that certain tumors have hypoxic zones that resist infiltration by T cells, which are capable of attacking and killing tumor cells, and that combination therapy with evofosfamide and anti-CTLA-4/anti-PD-1 treatment opens up the hypoxic zones to T cell infiltration."

Evofosfamide (also known as TH-302) is Threshold's proprietary, hypoxia-activated prodrug of a bis-alkylating agent that is preferentially activated under severe hypoxic tumor conditions, a feature of many solid tumors. In preclinical research conducted by Michael Curran, Ph.D., Assistant Professor at the University of Texas MD Anderson Cancer Center, evofosfamide has sensitized highly resistant solid tumor models to treatment with certain immune checkpoint inhibitors through evofosfamide-driven disruption of hypoxic zones. Specifically, hypoxia in the tumor microenvironment forms a barrier to T cell infiltration and fosters immunotherapy resistance in prostate cancer and other solid tumors.

The Phase 1 clinical trial is a single-arm, open label study that will enroll up to 69 patients with metastatic or locally advanced prostate cancer, metastatic pancreatic cancer, melanoma or HPV-negative squamous cell carcinoma of head and neck. Eligible patients will receive evofosfamide on Days one and eight of the first two cycles and ipilimumab on Day eight of a 28-day cycle. Immune-related Response Evaluation Criteria In Solid Tumors (irRECIST) response rate is the primary endpoint. Secondary endpoints include duration of response, progression-free survival, overall survival, safety, tolerability and pharmacokinetics. The study is open at MD Anderson Cancer Center in Houston, Texas. More details can be found here.

Conference Call
The Company and Dr. Curran will host a conference call today, June 13, at 4:15 p.m. Eastern Time / 1:15 p.m. Pacific Time. To participate by telephone, please dial 866.394.5751 (Domestic) or 213.660.0704 (International). The conference ID number is 39250039. A live and archived audio webcast can be accessed through the Investors section of the Company's website at www.thresholdpharm.com. The archived audio webcast will remain available on the Company's website for 30 days following the conference call.

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. Discussions remain ongoing with the Japanese PMDA regulatory agency on what additional clinical trials may be required to support submission of evofosfamide for the treatment of pancreatic cancer patients in Japan.

About Threshold Pharmaceuticals
Threshold is a clinical-stage biopharmaceutical company focused on the development of drugs and diagnostic agents targeting the tumor microenvironment of solid tumors and 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 all statements regarding the potential therapeutic applications for evofosfamide and its potential benefits, including as a potential treatment option in the metastatic or locally advanced prostate cancer, metastatic pancreatic cancer, melanoma or HPV-negative squamous cell carcinoma of head and neck settings. 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 risks that Threshold's evaluation of evofosfamide is at an early stage and it is possible that evofosfamide may not be found to be safe or effective in the initiated and/or planned Phase 1 clinical trials of evofosfamide or in any other studies of evofosfamide that Threshold may conduct, and that Threshold may otherwise fail to realize the anticipated benefits of its licensing of this product candidate; the risk that preclinical studies and Phase 1 clinical trials of evofosfamide may not predict the results of subsequent human clinical trials, including the risks that preclinical clinical data that suggest that evofosfamide that are active in xenograft models in mice could be attained in patients with an acceptable therapeutic index may not accurately predict whether a safe and effective dose can be attained in the patient populations that Threshold is targeting; 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; the ability of Threshold to enroll or complete ongoing and/or planned evofosfamide clinical trials; Threshold's potential inability to develop a formulation of evofosfamide with adequate quality that meets the specifications previously filed with the regulatory agency and that meets the need for testing in its clinical trials; issues arising in the regulatory process and the results of such clinical trials (including product safety issues and efficacy results); Threshold's dependence 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; and Threshold's need for and the availability of resources to develop its product 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 15, 2017 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.

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Source: Threshold Pharmaceuticals, Inc.