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Threshold Pharmaceuticals and Merck KGaA, Darmstadt, Germany Agree to Key Terms for the Licensing Back of All Rights to Evofosfamide to Threshold

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 01/11/16 -- Threshold Pharmaceuticals, Inc. (NASDAQ: THLD) today announced an update on its evofosfamide program including that Threshold and Merck KGaA, Darmstadt, Germany have agreed upon key terms for the licensing back of all rights to evofosfamide to Threshold. The companies have a global license and co-development agreement for evofosfamide, an investigational hypoxia-activated prodrug for the treatment of cancer, which was discovered and initially developed by Threshold.

The decision to return rights to evofosfamide to Threshold follows the unblinding of two Phase 3 clinical trials of evofosfamide (TH-CR-406 and MAESTRO) and a previously unplanned, subsequent interim futility analysis of a Phase 2 clinical trial of evofosfamide in patients with non-squamous non-small cell lung cancer (n-s NSCLC). As previously announced, both Phase 3 trials failed to meet the primary endpoint of demonstrating a statistically significant improvement in overall survival. The results of the MAESTRO trial will be presented at the American Society of Clinical Oncology 2016 Gastrointestinal Cancers Symposium during an oral presentation session scheduled to begin at 2:00 p.m. Pacific Time on Friday, January 22, 2016 (Abstract #193).

Following the topline results from the two Phase 3 clinical trials, Threshold and Merck KGaA, Darmstadt, Germany decided to unblind the Phase 2 clinical trial in n-s NSCLC and conduct an interim futility analysis. The Phase 2 trial was designed to enroll 440 patients with advanced n-s NSCLC. A total of 265 patients were enrolled and 112 events (deaths) were reported at the time of the interim analysis. An independent Data Safety Monitoring Board conducted the analysis and concluded that the trial is unlikely to reach its primary endpoint of improving overall survival with statistical significance. As a result, further enrollment in this trial will be closed. Additional findings from the interim analysis indicated that evofosfamide plus pemetrexed demonstrated longer progression-free survival (PFS) associated with a reduction in the risk of progression or death by approximately 30%. No new safety findings were reported. Data for this trial will be finalized and results presented at a future medical meeting.

"We are pleased to have agreed to key terms for the licensing back of all rights to evofosfamide to Threshold and we will share our plans for the future development of evofosfamide once our ongoing analyses of the data from the recently unblinded clinical trials are complete," said Barry Selick, Ph.D., Chief Executive Officer of Threshold. "In parallel, we continue to focus on prosecuting two Phase 2 clinical trials of tarloxotinib, our hypoxia-activated EGFR tyrosine kinase inhibitor, and to assess other strategic options for the company."

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. Threshold previously announced the outcomes of two Phase 3 studies (MAESTRO and TH-CR-406/SARC021) of evofosfamide stating that neither study met its primary endpoint. The related news release dated December 7, 2015, can be accessed on the company's website in the Investors/News Releases section http://investor.thresholdpharm.com/releases.cfm.

About Tarloxotinib Bromide
Tarloxotinib bromide (the proposed International Nonproprietary Name), 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 Pharmaceuticals, Inc. is a biotechnology company focused on the development of drugs 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 our website (www.thresholdpharm.com).

Forward-Looking Statements

Except for statements of historical fact, the statements in this press release are forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "may," "will," "expect," "plan," "believe," "predict," "future," or "continue," the negative of these terms and other comparable terminology. These statements are not historical facts but instead represent Threshold's beliefs regarding future results, many of which, by their nature, are inherently uncertain and outside Threshold's control. These include statements regarding the potential return to Threshold of the rights to evofosfamide previously licensed to Merck KGaA, Darmstadt, Germany; the potential continued development of evofosfamide by Threshold; Threshold's expectations regarding its ability to fund its operations through the release of preliminary results from its two Phase 2 trials of tarloxotinib, Threshold's expectations with respect to the results of its Phase 2 trial in advanced n-s NSCLC; that Threshold will be able to regain all rights in evofosfamide and the therapeutic potential of Threshold's product candidates; and that Threshold will be able to successfully develop evofosfamide, tarloxotinib, or any other product candidate. 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; risks related to Threshold's current dependence upon its collaborative relationship with Merck KGaA, Darmstadt, Germany, to further develop evofosfamide, including the risk that if such collaborative relationship is terminated, Threshold will be fully responsible for the costs of evofosfamide development and there can be no assurance Threshold would be able to do fund those costs, or to find another collaborator for the continued development of evofosfamide; the risks that the development of evofosfamide could be abandoned, and that even if its development continues, evofosfamide may never receive any marketing approvals; risks related to Threshold's ability to enroll or complete the ongoing Phase 2 trials of tarloxotinib and that tarloxotinib may not be found to be safe or effective in those trials 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 November 2, 2015 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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