Theseus Pharmaceuticals Investor Relations

Theseus Pharmaceuticals Announces FDA Clearance of Investigational New Drug Application for THE-630, a Pan-Variant KIT Inhibitor in Development for the Treatment of Gastrointestinal Stromal Tumors (GIST)

CAMBRIDGE, Mass., Nov. 1, 2021 /PRNewswire/ --Theseus Pharmaceuticals, Inc. ("Theseus"), a biopharmaceutical company focused on improving the lives of cancer patients through the discovery, development and commercialization of transformative targeted therapies, today announced U.S. Food and Drug Administration (FDA) clearance of an investigational new drug (IND) application to evaluate THE-630, the company's lead development candidate, in patients with gastrointestinal stromal tumors (GIST). THE-630 is a pan-variant inhibitor of the receptor tyrosine kinase KIT designed for patients with advanced GIST whose cancer has developed resistance to earlier lines of therapy.

"The IND clearance for THE-630 marks an important milestone for Theseus as we transition into a clinical-stage company," said Tim Clackson, Ph.D., president and CEO of Theseus Pharmaceuticals. "Patients with previously-treated GIST often have tumors that have developed more than one mutation in KIT that causes resistance to treatment, and we believe treatment with a kinase inhibitor that is active against all relevant mutations—that is, a pan-variant inhibitor—is a promising approach to address this key mechanism of resistance. We look forward to initiating the Phase 1/2 clinical trial and evaluating the potential that THE-630 may offer for patients with advanced GIST who have developed resistance to prior therapy."

THE-630 exhibits potent in vitro activity against all known classes of KIT activating and resistance mutations in GIST. In preclinical studies, THE-630 achieved predicted pan-variant KIT inhibitory blood concentrations at tolerable doses and induced significant anti-tumor activity. Theseus plans to initiate a Phase 1/2 dose escalation and expansion clinical trial of THE-630 in patients with previously treated advanced GIST between late fourth quarter 2021 and mid-first quarter 2022.

About Theseus Pharmaceuticals, Inc.
Theseus is a biopharmaceutical company focused on improving the lives of cancer patients through the discovery, development and commercialization of transformative targeted therapies. Theseus is developing next-generation tyrosine kinase inhibitors (TKIs): "pan-variant" targeted therapies that address all major drug resistance mutations. Theseus' lead product candidate, THE-630, is a pan-variant KIT inhibitor for the treatment of patients with advanced gastrointestinal stromal tumors (GIST), whose cancer has developed resistance to earlier lines of kinase inhibitor therapy. Theseus is also developing a fourth-generation, selective epidermal growth factor receptor (EGFR) inhibitor for C797S-mediated resistance to first- or later-line osimertinib treatment in patients with non-small cell lung cancer (NSCLC). For more information, visit www.theseusrx.com.

Cautionary Statement Regarding Forward Looking Statements
Certain statements included in this press release are not historical facts but are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook," and similar expressions that predict or indicate future events or trends or that are not statements of historical matters, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements include, but are not limited to, statements regarding Theseus' strategy, future operations, prospects and plans, the structure and timing of its planned clinical trial, expected milestones, market opportunity and sizing and objectives of management, including in relation to THE-630 and the planned Phase 1/2 does escalation and expansion clinical trial.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described under the caption "Risk Factors" in Theseus' final prospectus dated October 6, 2021 filed with the Securities and Exchange Commission (SEC) on October 7, 2021 and Theseus' other filings with the SEC. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements contained in this press release are based on the current expectations of Theseus' management team and speak only as of the date hereof, and Theseus specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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