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Molecular Templates Announces Dosing of First Patient in Phase 1 Expansion Study of MT-3724 in Diffuse Large B-Cell Lymphoma (DLBCL)

- Maximum Tolerated Dose of MT-3724 Identified

AUSTIN, Texas, Oct. 24, 2017 (GLOBE NEWSWIRE) -- Molecular Templates, Inc., (Nasdaq:MTEM) a clinical stage biopharmaceutical company focused on the discovery and development of Engineered Toxin Bodies (ETBs), today announced the dosing of the first patient in a Phase 1 expansion study of MT-3724, a first-generation ETB that targets the CD20 cell surface antigen present in a variety of lymphomas and leukemias. Strong evidence of anti-tumor activity in heavily pre-treated patients has been observed in Part 1 of the study.

“MT-3724 has shown activity in heavily pre-treated DLBCL patients with a median of greater than four prior therapies in the dose escalation portion of this study,” said Eric E. Poma, Ph.D., Chief Executive and Chief Scientific Officer of Molecular Templates. “We are pleased to begin dosing patients in the expansion cohort, which is designed to further characterize the efficacy and response rates in these difficult to treat patients.”

The Phase 1 study is a two-part study in patients with relapsed or refractory B-cell non-Hodgkin’s lymphoma or relapsed/refractory B-cell CLL. In Part 1, patients were treated with MT-3724 given as intravenous (IV) infusions at doses ranging from 5 mcg/kg up to 100 mcg/kg. The primary outcome measures are safety and tolerability, while secondary endpoints are pharmacokinetics (PK), pharmacodynamics (PD) and tumor response. The MTD was identified as 75 mcg/kg and this was supported by a dose-dependent clearance of CD20+ peripheral B cells, which is an acknowledged surrogate marker of efficacy.

Establishment of the MTD has triggered initiation of Part 2 of the study, in which relapsed or refractory DLBCL patients without high serum levels of Rituxan® will be treated with MT-3724 as a monotherapy at the MTD dose. The study has been designed to enroll up to 40 patients in total.

Part 2 of the study is being conducted at multiple centers across the United States including Memorial Sloan-Kettering Cancer Center in New York City, the MD Anderson Cancer Center in Houston, Texas, and the University of Arizona in Tucson, Arizona with data expected in the first half of 2018. Molecular Templates anticipates initiating a phase II monotherapy study in relapsed and refractory DLBCL patients in 2018 that could be pivotal in nature. The first patient was dosed at the University of Arizona. Additional information on the study, including inclusion/exclusion criteria, can be found at www.clinicaltrials.gov (NCT Identifier:

NCT02715843).

About MT-3724
MT-3724, Molecular Templates' lead drug candidate, is an immunotoxin that targets the CD20 cell surface antigen present in a variety of lymphomas and leukemias. CD20 is a non-internalizing receptor and MT-3724 is the first immunotoxin to induce internalization and destruction of CD20 positive cells to enter the clinic. MT-3724 is currently being investigated in a Phase 1 clinical trial in heavily pre-treated Diffuse Large B-cell Lymphoma (DLBCL) patients. More information is available at clinicaltrials.gov.

About Molecular Templates
Molecular Templates is focused on the discovery, development and commercialization of next-generation immunotoxins called Engineered Toxin Bodies (ETBs) for the treatment of cancers and other serious diseases. ETBs can induce internalization of normally non-internalizing receptors and possess the additional property of a unique cell killing mechanism. For additional information, please visit Molecular Templates' website at www.mtem.com.

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