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Molecular Templates, Inc. Announces Dosing of First Subject in Phase 1 Study of MT-6402 in PD-L1-Positive Solid Tumors

AUSTIN, Texas, July 09, 2021 (GLOBE NEWSWIRE) -- Molecular Templates, Inc. (Nasdaq: MTEM, "Molecular Templates" or "MTEM"), a clinical-stage biopharmaceutical company focused on the discovery and development of proprietary targeted biologic therapeutics, engineered toxin bodies (ETBs), today announced the dosing of the first subject in a Phase 1 study investigating MT-6402 in patients with PD-L1-positive solid tumors.

"We are excited to have dosed the first subject in the Phase 1 study for MT-6402, a third generation ETB, which is being developed as a potential treatment for patients with PD-L1-positive cancers. MT-6402 utilizes both our proprietary de-immunized toxin scaffold and antigen seeding technology," said Eric Poma, Ph.D., CEO and CSO of Molecular Templates. "The PD-1/PD-L1 axis is central to many tumors and targeting that axis with a new mechanism of action has an opportunity to provide meaningful benefit to patients. We look forward to providing an update on this study by year-end 2021."

The Phase 1 study for MT-6402 is planned as a multi-center, open-label, dose escalation and dose expansion trial in the United States and outside of the United States. Patients with confirmed PD-L1 expressing tumors or confirmed PD-L1 expression in the tumor microenvironment will be eligible to screen for enrollment. The starting dose is 16 mcg/kg. Following determination of the maximum tolerated dose (MTD) or recommended Phase 2 dose, expansion cohorts are planned to evaluate MT-6402 as a monotherapy in tumor-specific and tumor-agnostic cohorts. For more information on the Phase 1 study for MT-6402, refer to ClinicalTrials.gov identifier: NCT04795713.

About MT-6402

MT-6402 is an ETB consisting of a single chain variable fragment (scFv) with affinity for PD-L1, fused to the enzymatically active de-immunized Shiga-like toxin-A subunit (SLTA) and a class I antigen derived from the human cytomegalovirus (HCMV) pp65 protein. MT-6402 was designed to induce potent anti-tumor effects via PD-L1 targeting through multiple mechanisms that may overcome the limitations of the existing PD-L1 antibody therapies. In MTEM's preclinical studies, MT-6402 was found to specifically bind and kill both tumor and immune PD-L1 expressing cells in a manner consistent with SLTA mediated cellular cytotoxicity through ribosomal inactivation, independent of checkpoint inhibition. Additionally, MT-6402 alters the immunophenotype of targeted cells by delivering foreign class I antigen from CMV for presentation in complex with MHC class I, which may provoke a CMV-specific immune response against the targeted cells. MT-6402 may rehabilitate the tumor microenvironment (TME) and allow for immune recognition of tumors by destroying PD-L1-expressing immune cells in the TME.

About Molecular Templates

Molecular Templates is a clinical-stage biopharmaceutical company focused on the discovery and development of targeted biologic therapeutics. Our proprietary drug platform technology, known as engineered toxin bodies, or ETBs, leverages the resident biology of a genetically engineered form of Shiga-like Toxin A subunit to create novel therapies with potent and differentiated mechanisms of action for cancer and other serious diseases.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the "Act"). Molecular Templates disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Act's Safe Harbor for forward-looking statements. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Molecular Templates may identify forward-looking statements. Examples of such statements include, but are not limited to, statements regarding the safety or potential efficacy of Molecular Templates' drug or biologic candidates; the prospects of PD-L1 targeting therapies as a potential treatment; statements relating to the development of MT-6402; the expected timing of initiating and completing enrollment of cohorts and conducting the planned Phase 1 study of MT-6402; and Molecular Templates' belief that its proprietary biologic drug platform technology, or ETBs, provides for a differentiated mechanism of action that may address some of the limitations associated with currently available cancer therapeutics.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors including, but not limited to, the uncertainties inherent in the preclinical and clinical development process; Molecular Templates' ability to timely enroll patients in the Phase 1 study; whether Molecular Templates' cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; the ability of Molecular Templates to protect its intellectual property rights; risks from global pandemics including COVID19; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Molecular Templates' filings with the SEC. There can be no assurance that any of Molecular Templates' drug or biologic candidates will be successfully developed, manufactured or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market products, or that any of the forward-looking information provided herein will be proven accurate. Any forward-looking statements contained in this press release speak only as of the date hereof, and Molecular Templates specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.

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