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Molecular Templates, Inc. Announces Fast Track Designation Granted by FDA for MT-6402

AUSTIN, Texas, Nov. 18, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for MT-6402 for the treatment of patients with advanced non-small cell lung cancer (NSCLC) expressing PD-L1.

"Fast Track Designation is an acknowledgement from the FDA of the potential of MT-6402 to address a significant unmet need in NSCLC," said Roger Waltzman, Molecular Templates' Chief Medical Officer. "This designation will allow for continued contact with the FDA regarding the ongoing clinical program as well as future studies."

The Fast Track program is designed to accelerate the development and review of products such as MT-6402, which are intended to treat serious diseases and for which there is an unmet medical need. Fast Track designation enables more frequent communication with the FDA and may allow for further benefit from FDA accelerated programs such as priority review and/or rolling review.

MT-6402 is the first of MTEM's third generation ETBs to enter the clinic. It was designed to induce potent anti-tumor effects via PD-L1 targeting through multiple mechanisms that may overcome the limitations of the PD-L1 antibodies. MT-6402 is currently being evaluated in a multi-center, open-label, dose escalation and dose expansion Phase I trial in patients with solid tumors in the United States. Patient enrollment is currently ongoing. 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 basket cohorts.

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, including the anticipated benefits of Molecular Templates' next-generation ETBs compared to its first-generation ETBs; statements relating to the development and evaluation of MT-5111, MT-0169, and MT-6402; the expected timing of submitting various IND applications and conducting studies and generating data; Molecular Templates' receipt of future development, regulatory and sales milestones and royalty payments; the expected participation and presentation at upcoming conferences; the anticipated effects of the COVID-19 pandemic on Molecular Templates' ongoing clinical studies, manufacturing and preclinical development; 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; whether Molecular Templates' cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; Molecular Templates' ability to timely enroll patients in its clinical trials; the ability of Molecular Templates' to protect its intellectual property rights; risks from global pandemics including COVID-19; 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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