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Molecular Templates Announces IND Acceptance by FDA for MT-8421 ETB Program Targeting CTLA-4

AUSTIN, Texas, March 09, 2023 (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"), to create novel therapies with potent differentiated mechanisms of action for cancer, has received clearance by the United States Food and Drug Administration ("FDA") following review of its Investigational New Drug Application ("IND") to proceed for clinical testing of its novel MT-8421 ETB program targeting CTLA-4 in patients with relapsed/refractory solid tumors previously exposed to checkpoint inhibitors.

"MT-8421 represents a novel approach to target CTLA-4 in a wholly distinct manner from the current monoclonal antibody approaches. MT-8421 was designed to eliminate CTLA-4-expressing Tregs in the tumor microenvironment ("TME") through a direct cell-kill mechanism independent of the effector cell presence that antibodies rely upon while not effecting Tregs in the periphery, the major mechanism of antibody-mediated autoimmune toxicity," said Eric Poma, Chief Executive Officer and Chief Scientific Officer of MTEM.

Preclinical data from MT-8421 showed that in a transgenic mouse model expressing human CTLA-4 and bearing syngeneic subcutaneous tumors, MT-8421 treatment depleted immune suppressive Tregs in the TME but not in the periphery. MT-8421 was well tolerated in a non-human GLP primate toxicology study and achieved serum levels well-above projected IC_{50} concentrations for Tregs in the TME. MTEM expects to initiate a first-in-human phase I study with MT-8421 by mid-year 2023 at a starting dose of 32 mcg/kg.

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.

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 CTLA-4 targeting therapies as a potential treatment; statements relating to the development of MT-8421; the expected timing of initiating and completing enrollment of cohorts and conducting the planned Phase I study of MT-8421; and Molecular Templates' belief that its proprietary biologic drug platform technology, or ETBs, provides for a differentiated mechanism of action for cancer.

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, including the fact that interim results may not be indicative of future results; 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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