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Molecular Templates, Inc. Announces Dosing of First Subject in Phase I Study of TAK-169 in Relapsed/Refractory Multiple Myeloma

Milestone Triggers $10 Million Payment to Molecular Templates

AUSTIN, Texas, Feb. 19, 2020 (GLOBE NEWSWIRE) -- Molecular Templates, Inc. (Nasdaq: MTEM, "Molecular Templates" or "MTEM"), a clinical-stage biopharmaceutical company focused on the discovery and development of the company's proprietary engineered toxin bodies (ETBs), which are differentiated, targeted, biologic therapeutics for cancer and other serious diseases, today announced the initiation of dosing in a Phase I study investigating TAK-169 in patients with relapsed/refractory multiple myeloma. Co-developed with Takeda Pharmaceutical Company Limited ("Takeda"), TAK-169 is a potential first-in-class CD38-targeting ETB. As a result of achieving this milestone, MTEM will receive a $10 million payment from Takeda.

"TAK-169, which leverages MTEM's second generation, de-immunized ETB technology, represents a promising therapeutic approach for multiple myeloma patients with significant unmet medical needs. We are pleased that dosing is underway in the Phase I study," said Eric Poma, Ph.D., Molecular Templates' Chief Executive and Scientific Officer. "This product candidate is designed to deliver a potent, direct, cell-killing mechanism to cells that express CD38, a receptor that is known to be central to myeloma disease."

This study is a Phase 1, open-label, dose-escalation, multicenter study to evaluate TAK-169 in patients with relapsed or refractory multiple myeloma. The primary endpoints are to evaluate safety and tolerability. Secondary endpoints include preliminary efficacy, pharmacokinetic, pharmacodynamic, and immunogenicity measures. Patients will be followed up for 30 days after the last dose of study drug for a follow-up assessment. For more information, refer to ClinicalTrials.gov identifier: NCT04017130.

"TAK-169 has advanced to clinical development by pairing Takeda's multiple myeloma expertise with Molecular Templates' novel ETB technology," said Chris Arendt, Ph.D., Head, Oncology Therapeutic Area Unit, Takeda. "This program is a prime example of Takeda's emphasis on working with world-class partners to discover and develop transformational new therapies for multiple myeloma and other hematologic malignancies."

About TAK-169
TAK-169 is an ETB consisting of a single chain variable fragment (scFv) with affinity for CD38, fused to the enzymatically active de-immunized Shiga-like toxin-A subunit (SLTA). TAK-169 is designed to bind and kill CD38 expressing cells in a manner consistent with

SLTA mediated cellular cytotoxicity. TAK-169 has been specifically designed to avoid competition with and to overcome the primary mechanisms of tumor resistance to daratumumab, the first approved monoclonal antibody targeting CD38. In preclinical investigation TAK-169 has been shown to be active in the presence of daratumumab. As such, TAK-169 may have the potential to be combined with approved CD38 targeted therapies. TAK-169 mediated ribosomal inhibition and cell death take place intracellularly so changes in the tumor microenvironment, such as CD55/59 upregulation, which inhibit immune-mediated mechanisms such as antibody-dependent cell-mediated cytotoxicity (ADCC) or complement dependent cytotoxicity (CDC) are not expected to inhibit TAK-169 activity.

About the CD38 Co-Development Partnership with Takeda

On September 19, 2018, MTEM announced an agreement with Takeda for the joint development of CD38-targeted ETBs for the treatment of multiple myeloma. TAK-169, the lead development candidate, is a CD38-targeted ETB that resulted from a previous discovery collaboration between the two companies. Under the terms of the agreement, Takeda made an upfront payment of $30 million and Molecular Templates is eligible to receive development, regulatory and commercial milestone payments of up to $632.5 million if Molecular Templates exercises its co-development option or $337.5 million if Molecular Templates does not exercise or opts out of its co-development option. Takeda has also agreed to pay royalties on sales of the commercial product developed through the collaboration. Molecular Templates and Takeda will share equally in the development costs. MTEM has been awarded a $15.2 million grant from the Cancer Prevention and Research Institute of Texas (CPRIT) to fund development and manufacturing of CD38-targeted ETBs including TAK-169.

About Molecular Templates

Molecular Templates is a clinical-stage company focused on the discovery and development of targeted biologic therapeutics. Molecular Templates' 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 relating to the development of TAK-169; the expected timing of submitting various IND applications and conducting studies; and the Company's 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 the Company's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; the ability of the Company to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in the Company's filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.

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