

Molecular Templates Provides Corporate Update and Outlines 2020 Milestones

Three Products Advancing in the Clinic with Additional Pipeline Growth to Come from Internal Research and Partnerships

AUSTIN, Texas, Jan. 08, 2020 (GLOBE NEWSWIRE) -- Molecular Templates, Inc., (Nasdaq: MTEM) a clinical-stage biopharmaceutical company focused on the discovery and development of the Company's proprietary targeted biologic therapeutics, engineered toxin bodies (ETBs), provided a corporate update and outlined expected 2020 milestones.

"2019 was a year of growth for MTEM as we advanced our pipeline programs, established a new collaboration outside of oncology with a premier partner, and strengthened our balance sheet with a successful equity financing," said Eric Poma, Ph.D., Chief Executive and Chief Scientific Officer of Molecular Templates. "As we start 2020, we look forward to generating clinical data from three ongoing Phase 2 studies with MT-3724, an ongoing Phase 1 study for MT-5111, and a Phase 1 study with TAK-169. We expect to file an IND in 2H20 for MT-6402, our PD-L1-targeted ETB with antigen seeding capabilities, and we will continue to advance our earlier stage pipeline while making progress with our existing collaborations."

2019 Accomplishments, Status Updates, and Expected 2020 Milestones

MT-3724 (CD20 ETB)

- Candidate description
 - MT-3724 is a 1st generation ETB that utilizes wild-type Shiga-like toxin A (SLTA) genetically fused to an scFv to CD20 to bind, induce internalization, and destroy CD20-expressing tumor cells through ribosomal inactivation.
- 2019 accomplishments
 - In 2019, MTEM presented final results of the Phase 1/1b monotherapy study in lymphoma patients and initiated three Phase 2 studies in diffuse large B-cell lymphoma (DLBCL); a monotherapy study that has the potential to be pivotal and two combination studies, one with lenalidomide and the other with gemcitabine/oxaliplatin (GemOx).
 - The final Phase 1/1b results presented at the American Society of Hematology (ASH) annual meeting included safety data on doses from 5-100 μg/kg, and efficacy data on 13 serum rituximab negative (RTX-neg) DLBCL or mixed DLBCL/FL subjects of whom 5 responded (38% objective response rate) across the range of 5 to 50 μg/kg doses. Of the 5 responses, 2 were complete responses (CRs) and 3 were partial responses (PRs). Three patients had stable disease (including 2 patients with 49% and 47% tumor reductions) and 5 patients had progressive disease. Of the 5 serum RTX-neg subjects with DLBCL who received MT-3724 at 50 μg/kg, the maximum tolerated dose (MTD), 3 responded

- (2 CRs, 1 PR).
- The combination study with lenalidomide has demonstrated preliminary evidence of tolerability and efficacy with lenalidomide at standard doses and MT-3724 at 10 μg/kg. MT-3724 dosing at 25 μg/kg with lenalidomide is ongoing.
- The combination study with GemOx has demonstrated preliminary evidence of efficacy but grade 2 innate immune adverse effects were seen with standard doses of gemcitabine and oxaliplatin and 10 μg/kg doses of MT-3724. The study protocol has been amended to include a revised schedule where MT-3724 dosing is initially sequenced with GemOx dosing.
- Status updates and expected 2020 milestones
 - The potentially pivotal Phase 2 monotherapy DLBCL study is ongoing and is planned to enroll up to 100 patients. MTEM expects to announce updates on interim clinical results from this study and the ongoing lenalidomide and GemOx combination studies throughout 2020.

MT-5111 (HER2 ETB)

- Candidate description
 - MT-5111 is a 2nd generation ETB technology that utilizes a genetically engineered de-immunized Shiga-like toxin A-subunit (SLTA) to reduce the potential for innate and adaptive immunogenicity. MT-5111 directly kills HER2positive cells via ribosomal inactivation, a mechanism wholly distinct from approved HER2 targeted agents.
 - MT-5111 binds HER2 in the presence of trastuzumab and pertuzumab, creating the possibility of combining MT-5111 with other HER2 antibody-based agents.
 - MT-5111 is 55 kDa, almost a third smaller than traditional antibody and antibody drug conjugate (ADC) therapies, and, because of its smaller size, may have superior tumor penetration.
- 2019 accomplishments
 - In 2019, the IND for MT-5111 was accepted by the FDA and MTEM initiated a Phase 1 study, for which dosing began in 4Q19. MTEM also presented preclinical data on MT-5111 at the San Antonio Breast Cancer Symposium (SABCS).
- Status update and expected 2020 milestones
 - The Phase 1 study is ongoing with multiple sites open for enrollment. MTEM
 expects to announce interim clinical results from this study in 2Q20 and
 additional data from the dose escalation portion of the study in 4Q20.

TAK-169 (CD38 ETB)

- Candidate description
 - TAK-169 is a 2nd generation ETB that utilizes a genetically engineered deimmunized Shiga-like toxin A-subunit (SLTA) to reduce the potential for innate and adaptive immunogenicity. TAK-169 targets CD38, a poorly internalizing receptor expressed on myeloma cells, and directly kills CD38-expressing tumor cells via ribosomal inactivation.
 - Data in non-human primates suggest that TAK-169 can be dosed at higher doses than MT-3724 with a markedly reduced propensity of innate immune response compared with MT-3724.

 Preclinical data suggest that TAK-169 retains activity in the presence of daratumumab, an approved CD38 antibody.

• 2019 accomplishments

 In 2019, MTEM and partner Takeda presented preclinical data on TAK-169 at the American Association of Cancer Research (AACR) annual meeting, the IND for TAK-169 was accepted by the FDA, and Takeda initiated a Phase 1 study in relapsed/refractory multiple myeloma in 4Q19. In December 2019, TAK-169 received Orphan Drug Designation from the FDA.

Status update

Multiple sites are open for enrollment.

MT-6402 (PD-L1 ETB)

Candidate description

- MT-6402 is a 3rd generation ETB that targets PD-L1, a poorly internalizing receptor expressed on various solid tumors. MT-6402 shares the de-immunized scaffold used with 2nd-generation ETBs and is further engineered to deliver a viral foreign class I peptide (antigen seeding) to alter the tumor immunophenotype.
- MT-6402 utilizes Antigen Seeding Technology to deliver a foreign class I antigen derived from cytomegalovirus (CMV) inside the tumor for presentation on the tumor cell surface in complex with MHC class I molecules. MTEM has shown that antigen seeding allows CMV-reactive T-cells to recognize and destroy tumor cells. This T-cell response provides a mechanism of cell kill that is complementary to the ribosomal inactivation caused by the SLTA.

• 2019 accomplishments

- In 2019, MTEM presented preclinical data on its PD-L1 targeted ETBs at the AACR and Society for Immunotherapy of Cancer (SITC) annual meetings demonstrating potent anti-tumor effects on PD-L1+ tumor cells, good safety and pronounced pharmacodynamic effects in non-human primates, and a unique ability to alter the immunophenotype of tumors cells through antigen seeding.
- Status update and expected 2020 milestones
 - An IND is expected to be filed and the Phase 1 study for MT-6402 is expected to be initiated in 2H20.

Earlier stage pipeline

- Status update and expected 2020 milestones
 - MTEM continues to work on discovery of new ETBs against targets including CTLA-4, SLAMF-7, and CD45.
 - In 2020, MTEM expects to present preclinical data on new targets and new ETBs at conferences.

Corporate and Business Development

- 2019 accomplishments
 - On November 18, 2019, MTEM and Vertex Pharmaceuticals announced a strategic research collaboration to discover and develop novel targeted conditioning regimens that may enhance the hematopoietic stem cell transplant

process, including transplants conducted as part of treatment with *ex vivo* CRISPR/Cas9 gene editing therapies such as CTX001. Under the collaboration, MTEM will conduct research activities for the use of ETBs for up to two targets selected by Vertex. The initial research will be focused on discovering a novel conditioning regimen using MTEM's ETB technology platform. In addition, Vertex has an option to select a second target as part of the collaboration. Vertex made an up-front payment of \$38 million to MTEM, including an equity investment. MTEM is also eligible to receive future development, regulatory and sales milestones and option payments of up to \$522 million (across two targets) and tiered royalty payments on future sales.

- On November 21, 2019, MTEM announced the pricing of an underwritten equity offering, the net proceeds of which were approximately \$53.3 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by MTEM.
- Status update and expected 2020 milestones
 - MTEM has three ongoing collaborations: the co-development collaboration with Takeda for TAK-169, the multi-target collaboration with Takeda for the discovery and development of new ETBs against two undisclosed oncology targets, and the multi-target collaboration with Vertex for the discovery and development of new conditioning regimens. All three of these collaborations are expected to advance in 2020.

About Molecular Templates

Molecular Templates is a clinical-stage 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 relating to the development of MT-3724, MT-5111, TAK-169, and MT-6402; the expected timing of submitting various IND applications, conducting studies, dosing patients, and reporting additional updates on studies or data from various 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.

Investor Contact:

Adam Cutler
Chief Financial Officer
adam.cutler@mtem.com
862-204-4006

Source: Molecular Templates, Inc.



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