

PRESS RELEASE

Immatics Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for ACTengine® IMA203 TCR-T Monotherapy

- RMAT designation granted by FDA CBER for IMA203 cell therapy in multiple PRAME-expressing tumors including cutaneous and uveal melanoma, ovarian cancer and other cancer types
- Regulatory activities underway with an initial focus on a registration-directed trial in melanoma as step one to leverage the full breadth of PRAME

Houston, Texas and Tuebingen, Germany, October 24, 2023 – [Immatics N.V.](#) (NASDAQ: IMTX, “Immatics”), a clinical-stage biopharmaceutical company active in the discovery and development of T cell-redirecting cancer immunotherapies, today announced that its IMA203 TCR-T program has received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA Center for Biologics Evaluation and Research (CBER) in multiple relapsed and/or refractory HLA-A*02:01-positive and PRAME-expressing cancers, including cutaneous melanoma, uveal melanoma, endometrial carcinoma, synovial sarcoma, and ovarian cancer. IMA203 is a TCR-T cell therapy targeting PRAME, a protein frequently expressed in a large variety of solid tumors.

“The FDA RMAT designation for multiple indications underscores the broad potential of IMA203 and the benefits it may provide for advanced-stage solid tumor patients. This is an important regulatory milestone and a recognition of our clinical development progress for this program,” said Cedrik Britten, Chief Medical Officer of Immatics. “The close support from the FDA resulting from the RMAT status enhances our efforts to accelerate bringing IMA203 to cancer patients by enabling real-time discussions on patient populations, trial design and CMC.”

Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the development and review processes for promising pipeline products, including cell therapies, that includes all the benefits of Fast Track and Breakthrough designation programs. An investigational cell therapy is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse, or cure a serious or life-threatening disease; and preliminary clinical evidence indicates that the therapy has the potential to address unmet medical needs for that disease. Advantages of the RMAT designation include early interactions with the FDA that may be used to discuss potential surrogate or intermediate endpoints for accelerated approval and potential ways to satisfy post-approval requirements,



potential priority review of the biologics license application (BLA) and other opportunities to expedite development and review.

Based on publicly available information¹, it is the Company's understanding that this is the first time that FDA has granted a RMAT designation for an oncology drug candidate for more than two solid tumor indications. As of Sep 30, 2023, the U.S. FDA has received at least 238 requests for RMAT designations and granted 92².

About IMA203 and target PRAME

ACTEngine® IMA203 T cells are directed against an HLA-A*02:01-presented peptide derived from preferentially expressed antigen in melanoma (PRAME), a protein frequently expressed in a large variety of solid cancers, thereby supporting the program's potential to address a broad cancer patient population. Immatics' PRAME peptide is present at a high copy number per tumor cell and is homogeneously and specifically expressed in tumor tissue. The peptide has been identified and characterized by Immatics' proprietary mass spectrometry-based target discovery platform, XPRESIDENT®. Through its proprietary TCR discovery and engineering platform XCEPTOR®, Immatics has generated a highly specific T cell receptor (TCR) against this target for its TCR-based cell therapy approach, ACTEngine® IMA203.

ACTEngine® IMA203 TCR-T is currently being evaluated in three ongoing Phase 1b dose expansion cohorts in last-line patients: Cohort A IMA203 GEN1 monotherapy, Cohort B IMA203 in combination with an immune checkpoint inhibitor (deprioritized) and Cohort C IMA203CD8 GEN2 monotherapy, where IMA203 engineered T cells are co-transduced with a CD8αβ co-receptor.

About ACTEngine®

ACTEngine® is a personalized cell therapy approach for patients with advanced solid tumors. The patient's own T cells are genetically engineered to express a novel, proprietary TCR directed against a defined cancer target. The modified T cells are then reinfused into the patient to attack the tumor. The approach is also known as TCR-engineered cell therapy (TCR-T). All Immatics' ACTEngine® product candidates can be rapidly manufactured utilizing a proprietary manufacturing process designed to enhance T cell engraftment and persistence *in vivo*.

The ACTEngine® T cell products are manufactured at the Evelyn H. Griffin Stem Cell Therapeutics Research Laboratory in collaboration with UTHealth.

¹ Source: <https://bioinformant.com/rmat/>

² Source: FDA - <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/cumulative-cber-regenerative-medicine-advanced-therapy-rmat-designation-requests-received-fiscal>

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About Immatics

Immatics combines the discovery of true targets for cancer immunotherapies with the development of the right T cell receptors with the goal of enabling a robust and specific T cell response against these targets. This deep know-how is the foundation for our pipeline of Adoptive Cell Therapies and TCR Bispecifics as well as our partnerships with global leaders in the pharmaceutical industry. We are committed to delivering the power of T cells and to unlocking new avenues for patients in their fight against cancer.

Immatics intends to use its website www.immatics.com as a means of disclosing material non-public information. For regular updates, you can also follow us on [Twitter](#), [Instagram](#) and [LinkedIn](#).

Forward-Looking Statements:

Certain statements in this press release may be considered forward-looking statements. Forward-looking statements generally relate to future events or Immatics' future financial or operating performance. For example, statements concerning the timing of product candidates and Immatics' focus on partnerships to advance its strategy are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Immatics and its management, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Factors that may cause actual results to differ materially from current expectations include, but are not limited to, various factors beyond management's control including general economic conditions and other risks, uncertainties and factors set forth in filings with the SEC. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Immatics undertakes no duty to update these forward-looking statements. All the scientific and clinical data presented within this press release are – by definition prior to completion of the clinical trial and a clinical study report – preliminary in nature and subject to further quality checks including customary source data verification.



For more information, please contact:

Media

Eva Mulder or Charlotte Spitz

Trophic Communications

Phone: +31 65 2331 579

immatics@trophic.eu

Investor Relations

Sabrina Schecher, Ph.D.

Senior Director, Investor Relations

Phone: +49 89 262002433

InvestorRelations@immatics.com