



## Expansion of CARMA's Phase I Trial of MCY-M11

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### **CARMA Cell Therapies™ Expands Phase I Trial of Anti-Mesothelin mRNA CAR-PBMC Cell Therapy MCY-M11**

- *New parallel cohort will broaden evaluation of MCY-M11 in patients through inclusion of a preconditioning regimen and multiple dosing cycles*
- *Clinicians at Massachusetts General Hospital and Hackensack University Medical Center will join those at National Cancer Institute and Washington University at St. Louis to evaluate MCY-M11 in the ongoing Phase I clinical trial*
- *To date, ongoing first-in-human study has demonstrated promising tolerability of MCY-M11 and feasibility of rapid, one-day autologous manufacturing*

**GAITHERSBURG, MD, 18 AUGUST 2020** - MaxCyte, Inc., (LSE: MXCT, MXCL), a global cell-based therapies and life sciences company, today announces the expansion of subsidiary CARMA Cell Therapies' ongoing Phase I intraperitoneal delivery and dose-escalation trial of MCY-M11, its lead anti-mesothelin CAR-PBMC cell therapy candidate. The expansion will involve a new parallel cohort of patients and the initiation of two additional clinical sites.

The new parallel Phase I cohort will evaluate intraperitoneal delivery of MCY-M11 at escalating doses in additional patients with relapsed/refractory ovarian cancer and malignant peritoneal mesothelioma, with the addition of a preconditioning regimen of cyclophosphamide prior to MCY-M11 infusion. This parallel Phase I cohort with preconditioning will progress independently from the ongoing evaluation of MCY-M11 in the existing no-preconditioning Phase I cohort. The MCY-M11 Phase I trial will also allow for multiple treatment cycles where indicated for both future preconditioning and no-preconditioning patients.

New clinical sites for the study at Massachusetts General Hospital/Harvard Medical

School and Hackensack University Medical Center are joining existing sites at the National Cancer Institute at the National Institutes of Health and Washington University in St. Louis.

In May, encouraging preliminary results for MCY-M11, which support this study expansion and the pursuit of new strategies with the therapy, such as the addition of a preconditioning regimen and delivering multiple cycles of treatment to further enhance efficacy, were presented at the virtual ASCO meeting. Results to date also support the continued validation of MaxCyte's proprietary CARMA autologous cell therapy platform.

For the ASCO abstract, please visit: <https://meetinglibrary.asco.org/record/185279/abstract>.

Following the expansion of the Phase I trial, preliminary clinical data for the existing no-preconditioning MCY-M11 trial are anticipated in H2 2020.

"We are very pleased with the progress of this first-in-human trial to date, and have great hopes that we are moving closer towards bringing a more effective immunotherapeutic option for patients with solid tumors," said **Claudio Dansky Ullmann, MD, Chief Medical Officer of MaxCyte**.

#### **About MCY-M11**

MCY-M11 is a non-viral, mRNA-based anti-mesothelin CAR-PBMC cell therapy manufactured using un-manipulated peripheral blood mononuclear cells (PBMC). It is being evaluated in the clinic as treatment for high mesothelin expressing solid tumors. It is under ongoing development in a first-in human multi-center, non-randomized, open label, dose-escalation Phase I clinical trial evaluating the safety and preliminary efficacy of intraperitoneal infusions of MCY-M11 in individuals with platinum-resistant, high-grade, serous adenocarcinoma of the ovary, primary peritoneum or fallopian tube, or individuals with advanced peritoneal mesothelioma, with recurrence after prior chemotherapy. MaxCyte anticipates 27 study participants will be enrolled across the existing and the new parallel cohort. Interim results presented at the ASCO 2020 meeting show that intraperitoneal infusion of MCY-M11 is feasible, safe, and well tolerated. There have been no dose-limiting toxicities and no treatment related discontinuations or deaths and most reported treatment related adverse events have been Grades 1-2 per NCI CTCAE in three completed dose levels as a single agent in the existing cohort. Enrollment in the fourth dose level of the existing cohort is in progress and will run alongside with enrollment in the new parallel cohort that includes a preconditioning regimen. Multiple cycles of treatment will be allowed in both the fourth dose level of the existing cohort and at all dose levels in the new parallel preconditioning cohort. We currently anticipate preliminary clinical data in H2 2020. More information about the study can be found at [ClinicalTrials.gov](https://ClinicalTrials.gov) (Identifier: NCT03608618).

#### **About CARMA Cell Therapies**

Through its wholly owned subsidiary, CARMA Cell Therapies, MaxCyte is facilitating advancement of novel mRNA-based cell therapies for cancer and other diseases with

serious unmet needs. CARMA is a novel and proprietary platform for the development of non-viral, human messenger RNA (mRNA)-based, chimeric antigen receptor (CAR) or T-cell receptor (TCR) redirected immune cell therapies. CARMA [derived from CAR mRNA] utilizes MaxCyte's Flow Electroporation® technology for highly efficient, non-viral, delivery of one or more mRNA(s) into un-manipulated peripheral blood mononuclear cells (PBMCs) or isolated immune cells such as T- or NK-cells. CARMA offers the potential for a safer cell therapy, as a result of transient expression of receptor(s) and a non-viral delivery approach. At the start of 2020, MaxCyte established CARMA Cell Therapies as a wholly owned subsidiary to facilitate independent investment and new partnerships to advance the CARMA platform. MaxCyte has retained Locust Walk, a global life science strategic advisory and transaction firm. The Company expects CARMA to be self-funded by end of 2020. For more information, visit <https://www.maxcyte.com/carma-cell-therapies/>.

### **About MaxCyte**

MaxCyte is a clinical-stage global cell-based therapies and life sciences company. As the inventors of the premier cell-engineering enabling technology, the Company helps bring the promise of next-generation cell and gene-editing therapies to life. The Company's technology is currently being deployed by leading drug developers worldwide, including all of the top ten global biopharmaceutical companies. MaxCyte licences have been granted for more than 120 cell therapy programmes, with more than 90 licensed for clinical use, and the Company has now entered into eleven clinical/commercial license partnerships with leading cell therapy and gene editing developers. MaxCyte was founded in 1998, is listed on the London Stock Exchange (AIM:MXCT, MXCL) and is headquartered in Gaithersburg, Maryland, US. For more information, visit [www.maxcyte.com](http://www.maxcyte.com).

**This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (MAR).**

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