



# FDA IND Clearance for First Clinical Programme

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MaxCyte, Inc.

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## **MaxCyte, Inc.**

("MaxCyte" or the "Company")

### **MaxCyte Receives US FDA Investigational New Drug Clearance for First Clinical Programme**

*Company to conduct Phase I clinical study of MCY-M11, a CAR therapeutic,  
in patients with ovarian cancer and peritoneal mesothelioma*

**Gaithersburg, Maryland - 16 July 2018:** MaxCyte (LSE: MXCT, MXCR) announced that it has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) to begin a clinical study in the United States with its first wholly-owned chimeric antigen receptor (CAR) therapeutic candidate, MCY-M11.

MaxCyte also today provided an update on trading for the six months ended 30 June 2018. The Company is trading in line with expectations and seeing a significant acceleration in the number of partner programs advancing towards commercialisation-stage.

"The IND clearance marks an important milestone for MaxCyte. We are excited to advance MCY-M11, our first therapeutic candidate in solid tumours into the clinic and we hope that the upcoming study will serve as validation of our proprietary CARMA™ (CAR therapeutic) drug platform as a whole," said **MaxCyte CEO Doug Doerfler**. "This

initial study will help determine the safety and potential effectiveness of the CARMA platform, and if successful, will mark its place as a new autologous cell-therapy platform for developing improved targeted cell-based immune therapies."

The IND allows for a Phase I clinical study to evaluate the safety of MCY-M11 in individuals with relapsed/refractory ovarian cancer and peritoneal mesothelioma. The clearance is for the Company's first clinical study with MCY-M11, which is a drug candidate for next-generation CAR-engineered cell therapy. MCY-M11 is differentiated from traditional CAR therapies by its use of messenger RNA (mRNA) to engineer fresh peripheral blood mononuclear cells, allowing rapid manufacture and delivery back to the patient, without the need for a viral component or cell expansion. This cell therapy provides for transient expression, engineered with the potential to minimize the adverse side-effects seen in viral-based CAR therapies. MaxCyte anticipates commencing dosing of patients in H2 2018.

#### **About the CARMA (CAR Therapy) Platform**

CARMA is MaxCyte's unique and proprietary CAR therapy platform in immuno-oncology. The platform is used to develop CAR therapies for a broad range of cancer indications. It offers the potential to deliver autologous cell therapies across a wide range of targets with a much quicker turnaround to the patient than traditional autologous cell therapies. More information on MaxCyte's CARMA programme is available at <https://www.maxcyte.com/car/>.

#### **About MaxCyte**

MaxCyte is a global cell-based medicines and life sciences company applying its patented cell engineering technology to help patients with high unmet medical needs in a broad range of conditions. MaxCyte is developing novel CARMA therapies for its own pipeline. CARMA is MaxCyte's mRNA-based proprietary platform for autologous cell therapy. In addition, through its core business, the Company leverages its Flow Electroporation® Technology to enable its partners across the biopharmaceutical industry to advance the development of innovative medicines, particularly in cell therapy, including gene editing and immuno-oncology. The Company has placed its cutting-edge flow electroporation instruments worldwide, including with nine of the top 10 global biopharmaceutical companies, and has more than 55 partnered programme licenses in cell therapy including more than 25 licensed for clinical use. With its robust delivery technology, MaxCyte helps its partners to unlock the full potential of their products.

For more information, visit [www.maxcyte.com](http://www.maxcyte.com)

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