

Imugene's onCARlytics combination with Celularity's placental-derived off-the-shelf allogeneic CYCART-19 T cells preclinical data presented at SITC Annual Meeting

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**Sydney, Australia, & Florham Park, NJ 11 November 2022:** Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company and Celularity Inc. (Nasdaq: CELU) (Celularity), a clinical-stage biotechnology company developing placental-derived allogeneic cell therapies and biomaterial products, are pleased to announce that data from preclinical studies of Imugene's onCARlytics (CF33-CD19) oncolytic virus in combination with Celularity's placental-derived off-the-shelf allogeneic CYCART-19 T cells was presented at the renowned Annual Meeting of the Society for Immunotherapy of Cancer (SITC), held in Boston, USA on 8-12 November 2022.

Dr Anthony Park from Dr Saul Priceman's lab at City of Hope presented the poster, "CF33-CD19t oncolytic virus (onCARlytics) in combination with off-the-shelf allogeneic CYCART-19 T-cells targeting de novo CD19t expressing tumors."

Key findings of the presentation are as follows:

- onCARlytics can target triple-negative breast cancer cell line MDA-MB-468 to express CD19t as a CAR T cell target in a virus dose-dependent manner.
- CYCART-19 demonstrated efficacy in preclinical models against MDA-MB-468 expressing CD19t following onCARlytics infection.
- There was an increase in CYCART-19 activation and IL-2 production in a virus dose-dependent manner.
- Allogeneic CYCART-19 T cells produced less IFN- $\gamma$  compared to autologous CD19-CAR T cells after CD19t-expressing tumor killing.
- CD19t expression was detected in tumors following onCARlytics infection in vivo.
- CYCART-19 treatment 7 days post onCARlytics infection showed significant tumor regression compared to onCARlytics or T cells alone in a mouse xenograft model of triple-negative breast cancer.

The poster is available on Imugene's website, <https://www.imugene.com/conference-presentations> and Celularity's website, <https://www.celularity.com./press-releases>.



Imugene CEO/MD Leslie Chong said “When we embarked on the partnership with Celularity we were eager to investigate the combination of the cutting-edge technologies, Imugene’s onCARlytics and Celularity’s placental-derived allogeneic CAR-T (CYCART-19). The results presented at SITC further build our confidence as to the potential benefit to patients from these technologies and provide an excellent platform for further clinical development.”

Celularity Founder, Chairman and CEO Bob Hariri added, “We are encouraged by the potent cytolytic activity observed in the CYCART-19 preclinical models when combining Imugene's onCARlytics product with our placentally derived CYCART-19 cells. The cytokine secretion profile demonstrated by the CYCART-19 cells suggests this combination may elicit reduced CRS potential in patients compared to PBMC derived CAR-T products”.

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**About CYCART-19 T cells combination with onCARlytics**



Autologous chimeric antigen receptor (CAR) T cell therapy has shown impressive clinical responses against CD19+ B-Cell hematological malignancies and is being actively explored in the treatment of solid tumors. However, several barriers have precluded therapeutic responses in solid tumors, including limited tumor-restricted CAR targets and the immunosuppressive tumor microenvironment. We have recently reported the successful combination immunotherapy using a novel chimeric vaccinia-based oncolytic virus (OV), called onCARlytics (Imugene Limited) that is engineered to express a non-signaling truncated CD19 (CD19t) antigen for tumor-selective delivery, enabling de novo targeting of tumor cells by autologous CD19-CAR T cell<sup>1</sup>. One of the field's unanswered questions is whether treatment-naïve allogeneic CAR T cells are superior to cancer patient-derived T cells for product manufacturing to improve overall responses against solid tumors.

This combination strategy was evaluated using two allogeneic CAR T cell products generated from peripheral blood mononuclear cells (PBMC) and placental T cells, respectively. PBMC-derived CAR T cells were manufactured from normal healthy donors. CYCART-19 (Celularity Inc.) cells were derived from postpartum human placental T cells that are genetically modified to express the CD19 CAR followed by CRISPR-Cas9-mediated knockout of the endogenous T cell receptor (TCR) and expanded to produce multiple doses of allogeneic “off-the-shelf” treatment.

CYCART-19 T cells induced potent cytolytic activity against solid tumor cells infected with onCARlytics. Interestingly, while we observed comparable anti-tumor activity between PBMC-derived CD19-CAR T cells and CYCART-19, differences in cytokine secretion were detected. This warrants the possibility that the placenta-derived CAR T product may elicit reduced cytokine release syndrome (CRS) potential in patients with maintained or improved efficacy. This combination approach demonstrated in vivo anti-tumor response in human tumor xenograft models. In summary, our results have demonstrated that further development of this combination immunotherapy for the potential treatment of a wide array of solid tumors is warranted.

## References

<sup>1</sup> Warner SG, Kim SI, Chaurasiya S, O'Leary MP, Lu J, Sivanandam V, Woo Y, Chen NG, Fong Y. A Novel Chimeric Poxvirus Encoding hNIS Is Tumor-Tropic, Imageable, and Synergistic with Radioiodine to Sustain Colon Cancer



*Regression. Mol Ther Oncolytics. 2019 Apr 11;13:82-92. doi: 10.1016/j.omto.2019.04.001. PMID: 31061881; PMCID: PMC6495072.*

## **About Imugene (ASX: IMU)**

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

*Release authorised by the Managing Director and Chief Executive Officer  
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## **About Celularity**

Celularity Inc. (Nasdaq: CELU) headquartered in Florham Park, N.J., is a clinical-stage biotechnology company leading the next evolution in cellular medicine by developing allogeneic cryopreserved off-the-shelf placental-derived cell therapies, including therapeutic programs using unmodified natural killer (NK) cells, genetically modified NK cells, T-cells engineered with a CAR (CAR-T cells), and mesenchymal-like



adherent stromal cells (MLASCs). These therapeutic programs target indications in cancer, infectious and degenerative diseases. In addition, Celularity develops and manufactures innovative biomaterials also derived from the postpartum placenta. Celularity believes that by harnessing the placenta's unique biology and ready availability, it can develop therapeutic solutions that address significant unmet global needs for effective, accessible, and affordable therapies.

### **Celularity Forward-Looking Statements**

*This press release includes "forward-looking statements" within the meaning of U.S. The Private Securities Litigation Reform Act of 1995, as well as within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward-looking statements," including those relating to future events. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "can," "contemplate," "continue," "could," "estimate," "expect," "forecast," "intends," "may," "might," "outlook," "plan," "possible," "potential," "predict," "project," "seek," "should," "strive," "target," "will," "would" and the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. The forward-looking statements in this press release include statements regarding the ability of CYCART-19 in combination with onCARlytics to elicit reduced CRS potential, among others. Many factors could cause actual results to differ materially from those described in these forward-looking statements, including but not limited to: the inherent risks in biotechnological development, including with respect to the development of novel cellular therapies, and the clinical trial and regulatory approval process; and risks associated with Celularity's current liquidity, as well as developments relating to Celularity's competitors and industry, along with those risk factors set forth under the caption "Risk Factors" in Celularity's annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 31, 2022, as amended on July 15, 2022, and other filings with the SEC. These risks and uncertainties may be amplified by the COVID-19 pandemic, recent downturn in the U.S. capital markets and inflation. If any of these risks materialize or underlying assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Celularity does not presently know, or that Celularity currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. In addition, these forward-looking statements reflect Celularity's current expectations, plans, or forecasts of future events and views as of the date of this communication. Subsequent events and developments could cause assessments to change. Accordingly, forward-looking statements should not be relied upon as representing Celularity's views as of any subsequent date, and Celularity undertakes no obligation to update forward-looking statements to reflect events or circumstances after the date hereof, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.*