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# Avalon GloboCare Provides Updates on its Lead Scientific and Clinical Programs in CAR T-Cell Therapy and COVID-19

- *Completed Phase I Clinical Study of 4-1BB Based Anti-CD19 CAR-T Therapy for Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia; Achieved 90% Complete Remission (CR) Rate with Minimum Toxicity or Adverse Side Effects*
- *Successfully Completed Pre-Clinical Research On AVA-011, Including Tumor Cytotoxicity Studies; Expect to Launch First-In-Human Trial in Q1 2021*
- *Filed Three Provisional Patents on Unique QTY Code Protein Design Platform that Combats the Cytokine Storm Associated With COVID-19 Lung Damage and Mortality*
- *Advances Novel Intranasal and Oral COVID-19 Vaccine Candidate*

FREEHOLD, N.J., July 13, 2020 (GLOBE NEWSWIRE) -- Avalon GloboCare Corp. (NASDAQ: AVCO), a clinical-stage global developer of cell-based technologies and therapeutics, today announced an update on its four scientific research and clinical development programs in cell therapy and COVID-19 related initiatives, including AVA-001 and AVA-011 (FLASH-CAR™), that leverage individualized CAR (Chimeric Antigen Receptor) T-cell therapy for immuno-oncology, as well as AVA-Trap™ for mitigating COVID-19 “cytokine storm,” and S-layer based COVID-19 vaccine development.

## **AVA-001**

Avalon has successfully completed a Phase I first-in-human clinical study of its leading CAR T-cell therapy candidate, AVA-001 (National Institute of Health clinical trial registration number: NCT03952923). AVA-001 is a third generation CAR T-cell therapy which involves the 4-1BB (or CD28) co-stimulation signaling pathway. Nine out of ten patients with relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL) have achieved complete remission (CR rate of 90%) within one month after receiving one dose of AVA-001 CAR T-cell therapy. The treatment with AVA-001 was generally well tolerated with minimal adverse side effects: no neurotoxicity or greater than Grade-1 cytokine release syndrome was observed in this cohort of patients treated with AVA-001. All patients who achieved CR successfully proceeded to allogeneic bone marrow transplant with curative intent. Accessory laboratory testing that accompanied this pilot clinical study has demonstrated evidence of enhancement in CAR T cell persistence and protection against CAR T cell exhaustion. This paradigm of bridging CAR T-cell therapy to bone marrow transplant creates a new therapeutic horizon with curative potential for patients with relapsed/refractory B-ALL and other hematologic cancers. Avalon is in the process of extending AVA-001 CAR T-cell therapy to the next phases of clinical development.

## **AVA-011 (FLASH-CAR™)**

Avalon's FLASH-CAR™ uses next generation CAR technology to modify patients' T-cells and natural killer (NK) cells using a ribonucleic acid (RNA)-based platform rather than a viral vector. Avalon's RNA-based CAR technology is designed to rapidly create personalized CAR therapies in 1 to 2 days compared to the 10- to 14-day bio-manufacturing time necessary to generate currently available CAR-T cellular immunotherapy. Avalon's FLASH-CAR™ technology is also designed to reprogram the immune cells to hone in on multiple crucial cancer cell targets, called tumor antigens, to potentially achieve superior therapeutic effect. Avoiding the use of viral vectors and complicated bio-processing procedures significantly reduces manufacturing costs, resulting in a more affordable and potentially breakthrough therapy for cancer patients. The FLASH-CAR™ technology can also be used to generate "off-the-shelf," universal cell therapy that has the potential to reach even more patients. Avalon's first FLASH-CAR™ platform candidate, AVA-011, targets both CD19 and CD22 tumor antigens on cancer cells. Pre-clinical research on AVA-011, including tumor cytotoxicity studies, has been successfully completed and Avalon is immediately entering the process development stage to generate clinical-grade CAR-T and CAR-NK cells for use in human clinical trials. Avalon expects to begin a first-in-human clinical trial with AVA-011 for the treatment of relapsed/refractory B-cell lymphoblastic leukemia (B-ALL) and non-Hodgkin lymphoma in the first quarter of 2021. The goal is to apply AVA-011 as a bridge to bone marrow stem cell transplant therapy with curative potential for patients with these blood cancers.

Avalon GloboCare, has established the **Avalon Combat COVID-19 Taskforce ("ACCT")** to expand and accelerate scientific/clinical development on multiple fronts to help combat the COVID-19 global pandemic through a strategic combination of therapeutic and vaccine approaches as follows:

### **AVA-Trap™**

Avalon has engaged with Massachusetts Institute of Technology (MIT) to co-develop a QTY therapeutic platform against the "cytokine storm" which causes lung damage and other organ failure associated with COVID-19. Cytokines are small protein molecules in the body required to regulate and maintain proper physiological functions. In some life-threatening diseases, however, cytokines are released in vast excess (also known as "cytokine storm") leading to devastating damage to vital tissues and organs. A prime example is the widely recognized SARS-CoV-2 (COVID-19)-induced "cytokine storm," which can lead to acute respiratory distress syndrome, lung fibrosis, multi-organ failure and death. The pre-clinical result has been published in the journal QRB Discovery (Cambridge University Press). Three USPTO provisional patents have been filed based on the unique QTY code protein design platform that uses six water-soluble variant cytokine receptors which have been successfully designed and tested to show binding affinity to the respective cytokines. Avalon's AVA-Trap™ therapeutic program is currently entering animal model testing followed by expedited clinical studies with the goal of providing an effective therapeutic option to combat COVID-19 and other life-threatening conditions involving cytokine storms.

### **Intranasal and Oral COVID-19 Candidate Vaccine**

Formed a strategic partnership program between Avalon GloboCare and the University of Natural Resources and Life Sciences (BOKU) in Vienna, Austria. The goal is to co-develop an S-layer vaccine that can be administered by an intranasal or oral route against SARS-CoV-2 (COVID-19). This partnership is led by BOKU's Professor Uwe B. Sleytr, an eminent

member of the Austrian Academy of Sciences, who is a pioneer of applied surface layer (“S-layer”) nanotechnology, based on the repetitive protein structures that make up the outer surface of microbial cells. This vaccine strategy has the dual advantages of ease of manufacturing and delivery. The candidate vaccine is derived from a fusion of an S-layer viral particle mimic with the SARS-CoV-2 spike protein and could be delivered non-invasively via the nasal or oral passageways, rather than a needle-based injection into the muscle or under the skin. The S-layer protein-based vaccine is expected to both decrease the severity of a SARS-CoV-2 infection—preventing the more severe respiratory inflammation and organ damage seen in many COVID-19 patients—and build immunity against the virus.

Substantial progress has been made by developing the proprietary techniques necessary to synthesize conjugate vaccines consisting of an S-layer artificial viral envelope linked to a viral antigen, eliciting immune-protective antibody responses. Avalon plans to complete the proof-of-concept pre-clinical studies in 2020, followed by first-in-human clinical study of this candidate vaccine during 2021. In addition, Avalon plans to utilize S-layer technology to accelerate additional vaccine programs for other respiratory infections including different strains of the flu (influenza A/B), respiratory syncytial virus (RSV), and other viruses. Avalon is also actively exploring other practical uses of S-layer technology including targeted drug delivery, diagnostic devices, and therapeutic applications.

“We are excited and encouraged by the progress in advancing our scientific and clinical programs targeting immune-oncology and COVID-19,” stated David Jin, M.D., Ph.D., President and Chief Executive Officer of Avalon GloboCare. “As an active, clinical-stage company with innovative technology, productive partnerships and exceptional talent, we are committed to delivering effective execution and leadership to combat cancer and COVID-19,” added Dr. Jin.

### **About Avalon GloboCare Corp.**

Avalon GloboCare Corp. (NASDAQ: AVCO) is a clinical-stage, vertically-integrated, leading CellTech bio-developer dedicated to advancing and empowering innovative, transformative immune effector cell therapy, exosome technology, as well as COVID-19 related diagnostics and therapeutics. Avalon also provides strategic advisory and outsourcing services to facilitate and enhance its clients' growth and development, as well as competitiveness in healthcare and CellTech industry markets. Through its subsidiary structure with unique integration of verticals from innovative R&D to automated bioproduction and accelerated clinical development, Avalon is establishing a leading role in the fields of cellular immunotherapy (including CAR-T/NK), exosome technology (ACTEX™), and regenerative therapeutics. For more information about Avalon GloboCare, please visit [www.avalon-globocare.com](http://www.avalon-globocare.com).

### **Forward-Looking Statements**

Certain statements contained in this press release may constitute "forward-looking statements." Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors as disclosed in our filings with the Securities and Exchange Commission located at their website (<http://www.sec.gov>). In addition to these factors, actual future performance, outcomes, and results may differ materially because of more general factors including (without limitation) general industry and

market conditions and growth rates, economic conditions, and governmental and public policy changes. The forward-looking statements included in this press release represent the Company's views as of the date of this press release and these views could change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of the press release.

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