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Avalon GloboCare Provides Updates on its Lead Clinical Programs in CAR-T Therapy and Exosome-Based Regenerative Therapeutics

- *CD19 CAR-T candidate, AVA-001, has entered first-in-human clinical study for relapsed/refractory B-cell acute lymphoblastic leukemia and non-Hodgkin lymphoma in July 2019*
- *Next-generation, transposon-engineered, multi-targeted CAR-T candidate, AVA-101, has entered process development and validation phase; expect to launch first-in-human trial in Q1 2020*
- *Accelerate clinical development of exosome-based oncology and regenerative therapeutic programs, AVA-201 and AVA-202*

FREEHOLD, N.J., July 15, 2019 (GLOBE NEWSWIRE) -- Avalon GloboCare Corp. (NASDAQ: AVCO), a leading global developer of cell-based technologies and therapeutics, today announced an update on its four clinical programs in cellular therapy, including AVA-001 and AVA-101, that leverage individualized CAR (Chimeric Antigen Receptor) T-cell therapy for immuno-oncology, as well as AVA-201 and AVA-202 exploring novel development with stem cell derived exosomes.

AVA-001

Avalon initiated its first-in-human clinical trial of CD19 CAR-T candidate, AVA-001, in July 2019 at the Hebei Yanda Lu Daopei Hospital and Beijing Lu Daopei Hospital in China, the world's single largest CAR-T treatment network with over 600 patients being treated with CAR-T, for the indication of relapsed / refractory B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin's Lymphoma (NHL). The significance of CAR-T cells is that they have been engineered to express a receptor (CAR) that recognizes a specific cancer surface target to attack. Unlike traditional small molecule or biologic treatments, the autologous CAR-T therapies are specifically manufactured for each individual patient. The Avalon clinical trial AVA-001 could result in a more powerful delivery mechanism designed to treat the individual patient. The AVA-001 candidate uses the 4-1BB (CD137) co-stimulatory signaling pathway, conferring strong anti-cancer activity as demonstrated during the pre-clinical study. It also features a shorter bio-manufacturing time. This process starts with the extraction of T cells from the individual patient which are turned into CAR-T cells that are targeted to recognize and destroy cancer cells. A shortened development cycle empowers the clinicians to provide treatment sooner to patients with hematologic malignancy. Avalon is projected to recruit 20 patients (under registered clinical trial NCT03952523) for safety and efficacy studies.

AVA-101

Avalon's proprietary, transposon-based, multi-targeted CAR-T candidate, AVA-101, will enter the pre-clinical process development and validation phase during Q3 of 2019 as scheduled. This next-generation CAR-T candidate features non-viral, transposon-engineered CAR-T with multiple anti-cancer targets, as well as possessing molecular safety-switch mechanism to minimize side effects, such as cytokine release syndrome and neurotoxicity, which are often associated with CAR-T cellular therapy and can have debilitating effects for patients. Avalon anticipates to launch the first-in-human clinical trial of this next-generation of safer and more efficacious CAR-T candidate during Q1 of 2020.

AVA-201

Since the discovery of saliva-based exosome-containing [miR-185](#) as "liquid biopsy" diagnostic biomarker for oral leukoplakia and oral cancer, Avalon has further developed a novel therapeutic candidate, AVA-201, for oral cancer. Using engineered mesenchymal stem cells as the "bio-factory" to mass-produce miR-185, which functionally serves to suppress cancer cell proliferation, invasion and migration, in the cell culture system, the resulting miR-185 enriched exosomes (AVA-201) were isolated and externally applied to the oral leukoplakia lesions in animal models as a proof-of-concept study. The compelling result of inhibiting cancer progression by AVA-201 was recently published in *Artificial Cells, Nanomedicine, and Biotechnology: An International Journal*, titled "Delivery of Mesenchymal Stem Cells-Derived Extracellular Vesicles with Enriched miR-185 Inhibits Progression of OPMD," which was also presented at the 2019 ISEV Conference in Kyoto, Japan. Avalon plans to launch the first-in-human clinical trial for AVA-201 during Q4 of 2019 with the expectation to move toward regulatory filing in Q4 of 2020.

AVA-202

Avalon has recently completed the standardized bio-production process of tissue-specific, clinical-grade exosomes, a [co-development endeavor](#) with Weill Cornell Medicine, with a focus on angiogenic exosomes derived from endothelial cells. These exosomes have demonstrative ability to regenerate tissues, specifically blood vessel formation and wound healing. Avalon is further leveraging this technology platform to develop this clinical-grade, exosome-based therapeutic candidate, AVA-202, and plans to initiate international multi-centered clinical studies in unmet medical areas of vascular diseases and wound healing, including treatment of diabetic foot ulcer, during Q4 of 2019.

In addition to the clinical development of AVA-202, the commercialization phase of [Avalon's ACTEX™](#)-based product development is underway to enter the markets of skin care, scar removal, and hair growth.

"We are pleased to provide updates on our progress in advancing clinical studies using our cellular therapeutic platforms in CAR-T and stem cell derived exosomes," stated David Jin, M.D., Ph.D., President, Chief Executive Officer and Co-founder of Avalon GloboCare. "We have successfully evolved into an active clinical stage company which we have the technology, partnerships and talent, all committed to delivering clinical execution and leadership in the areas of cellular immunotherapy and exosome technology," added Dr. Jin.

About Avalon GloboCare Corp.

Avalon GloboCare Corp. (NASDAQ: AVCO) is a leading CellTech bio-developer dedicated to advancing and empowering innovative, transformative exosome technologies and cellular therapeutics. Avalon also provides strategic advisory and outsourcing services to facilitate and enhance its clients' growth, development, as well as competitiveness in both the domestic and global healthcare markets. Through its subsidiaries, namely GenExosome Technologies Inc. and Avactis Biosciences Inc., Avalon is establishing a leading role in the fields of exosome-based diagnostics ("liquid biopsy"), cellular immunotherapy (including CAR-T/CAR-NK), and regenerative medicine.

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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