Cellular Biomedicine Group Announces Phase I Results from CAR-T Immuno-Oncology Clinical Development Programs

SHANGHAI, China and PALO ALTO, Calif., March 25, 2015 /GlobeNewswire/ -- Cellular Biomedicine Group Inc. (NASDAQ: CBMG) ("CBMG" or the "Company"), a biomedicine firm engaged in the development of effective treatments for degenerative and cancerous diseases, today announced clinical data from its CAR-T immuno-oncology clinical development programs. The data will be discussed by Dr. Wei (William) Cao, PhD, BM, Chief Executive Officer of Cellular Biomedicine Group, at the 2015 Annual Regen Med Investor Day on March 25 in New York City.

Dr. Cao commented, “We are very pleased with the efficacy and toxicity profile of our CAR-T technology, given the advanced stage of the cancer patients in the trials. With over 3.5 million new cancer patients diagnosed every year in China, developing safer and more effective cancer immunotherapy programs with leading hospitals will serve urgent unmet medical needs. We look forward to additional progress in advancing our CAR-T cell pipeline with further clinical development of our CD19, CD20, CD30 and EGFR-HER1 constructs.”

About the Trials
The CAR-T trials were designed and conducted by Chinese PLA General Hospital ("PLAGH", Beijing, also known as “301 Hospital”), led by Principal Investigator Wei Dong Han, MD, PhD, head of PLAGH’s cancer immunotherapy department. They studied genetically engineered lymphocyte therapy in treating patients with B-cell leukemia or lymphoma that is relapsed (after stem cell transplantation or intensive chemotherapy) or refractory to available therapeutics. The studies recruited male and female subjects with CD19+ and CD20+ B cell malignancies with no available curative treatment options (such as autologous or allogeneic SCT) that had limited prognosis (several months to < 2 year survival) with currently available therapies.

CAR-T CD19 for Acute Lymphocytic Leukemia (B-cell ALL) Data Analysis
Nine adult patients with relapsed or chemotherapy-refractory B-cell lineage acute lymphocytic leukemia (B-cell ALL) were enrolled in this CAR-CD19 T cell therapy trial. Results showed a complete response (CR) rate of 22.2% (two out of nine patients) and a partial response (PR) rate of 44.4% (four out of nine patients) for an overall response rate (ORR) of 66.7% (six out of nine patients). Further subgroup analysis showed an overall response rate (ORR) of 71.5% (five out of seven patients) in the six CD19 patients with extramedullary involvement and one patient with no extramedullary lesions and treated with autologous CAR-CD19 T cell therapy. In the six CD19 patients with extramedullary leukemia involvement or bulky adenopathy, an overall response rate (ORR) of 66.7% (four out of six patients) was achieved. Two of the nine patients with extramedullary lesions received allogeneic CAR-CD19 T cell therapy (CBM-C19.a1) and had converted mixed to complete donor chimerism at the onset of graft-versus-host disease (GVHD). One of those patients eventually died of GVHD, but the other gradually reached a complete hematologic remission and a partial regression of her extramedullary leukemic lesions. There were two Grade 2-3 toxicities and GVHD Grade 4 toxicities.

This study is registered at www.clinicaltrials.gov as NCT01864889.
CAR-T CD20 for Advanced Diffuse Large B Cell Lymphoma (DLBCL) Data Analysis
The Company also summarized the results of a Phase I clinical trial on CAR-CD20 T cell therapy (CBM-C20.1), which enrolled seven patients with chemotherapy refractory advanced diffuse large B cell lymphomas (DLBCL). One of the two patients with no bulky tumors achieved a 14-month durable and ongoing complete remission by cell infusion only, and another achieved a 6-month tumor regression achieving a complete response (CR) rate of 50% (one out of two patients) and an overall response rate (ORR) of 100% (two out of two patients). Of those patients with bulky tumor burden, four of five patients were evaluable for clinical efficacy. Of those four patients, three achieved three to six month tumor regression for an overall response rate (ORR) of 75% (three out of four patients).

Delayed toxicities related to CAR-CD20 cell infusion are directly correlated to tumor burden, and mainly included, but were not limited to, curable cytokine release symptoms and tumor lysis symptoms, and these results were achieved by combining debulking conditioning regimens in advanced DLBCL patients with bulky tumors. Overall there were three Grade 2-3 toxicities and one Grade 4 toxicity.


Further details of the clinical data may be viewed in the Company’s most recent presentation filed on Form 8k with the SEC, which can be found on the Company’s website at the following link, http://cellbiomedgroup.com/investor-relations/investment-overview/ under SEC filings or presentations.

The Company expects to release Phase I clinical data in the third quarter of 2015 from its clinical studies of the CAR-T constructs targeting CD30-positive Hodgkin’s lymphoma and EGFR-HER1-positive advanced lung cancer.

About Cellular Biomedicine Group
Cellular Biomedicine Group, Inc. develops proprietary cell therapies for the treatment of certain degenerative diseases and cancers. Our developmental stem cell, progenitor cell, and immune cell projects are the result of research and development by scientists and doctors from China and the United States. Our flagship GMP facility, consisting of eight independent cell production lines, is designed, certified and managed according to U.S. standards. To learn more about CBMG, please visit: www.cellbiomedgroup.com

Forward-Looking Statements
Statements in this press release relating to plans, strategies, trends, specific activities or investments, and other statements that are not descriptions of historical facts may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking information is inherently subject to risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, which include, but are not limited to, risk factors inherent in doing business. Forward-looking statements may be identified by terms such as "may," "will," "expects," "plans," "intends," "estimates," "potential," or "continue," or similar terms or the negative of these terms. Although CBMG believes the expectations reflected in the forward-looking statements are reasonable, they cannot guarantee that future results, levels of activity, performance or achievements will be obtained. CBMG does not have any obligation to update these forward-looking statements other than as required by law.
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