NEWS RELEASE

Angiocrine Bioscience Announces FDA Regenerative Medicine Advanced Therapy (RMAT) Designation Granted to AB-205 (Universal E-CEL® Cell Therapy) to Treat Organ Vascular Niche Injuries for the Prevention of Severe Toxicities in Lymphoma Patients undergoing Curative High-Dose Therapy with Autologous Stem Cell Transplantation

San Diego, CA, November 11, 2020 /PRNewswire/ Angiocrine Bioscience Inc., a clinical-stage biopharmaceutical company today announced that the U.S. Food and Drug Administration (FDA) granted the Regenerative Medicine Advanced Therapy (RMAT) designation for AB-205, for "the treatment of organ vascular niche injuries to prevent or reduce severe regimen-related toxicities (SRRT) in patients with Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL) undergoing high-dose therapy (HDT) and autologous hematopoietic stem cell transplantation". Based on its Phase 2 trial results, Angiocrine expects to initiate a single pivotal registration Phase 3 trial in 2021 involving leading cancer centers in North America and Europe.

"The RMAT designation speaks to the clinical meaningfulness and the promising efficacy data and safety profile of AB-205 based on our Phase 1b/2 study. This is an important step in accelerating the development of AB-205 towards its first market approval," commented Paul Finnegan, MD, Angiocrine's CEO. "We appreciate the thorough assessment provided by the FDA reviewers and the support from our partner, the California Institute for Regenerative Medicine." Angiocrine was awarded a $6 million grant from CIRM in 2019 for the clinical development of AB-205.

About Regenerative Medicine Advanced Therapy (RMAT) Designation

Established under the 21st Century Cures Act, the RMAT designation was established to facilitate development and expedite review of cell therapies and regenerative medicines intended to treat serious or life-threatening diseases or conditions. Advantages include the benefits of the FDA's Fast Track and Breakthrough Therapy Designation programs, such as early interactions with the FDA to discuss potential surrogate or intermediate endpoints to support accelerated approval.

About HDT-AHCT

High-dose therapy and autologous hematopoietic cell transplantation (HDT-AHCT) is considered a standard-of-care therapy for patients with aggressive systemic Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). Although efficacious and considered a potential cure, HDT-AHCT is associated with severe regimen-related toxicities (SRRT) that increase patient morbidity and risk for mortality, especially in the aging population. Effective prevention of SRRT may lead to more patients being eligible for a potential cure through HDT and stem cell transplantation.

About SRRT – Consequences of Diffuse Injury to the Organ Vascular Niches

The human body is capable of renewing, healing and restoring organs. For example, the human oral-GI tract renews its lining every 3 to 7 days. Both the organ renewal and healing processes are dependent on organ stem cell vascular

niches made up of stem cells, endothelial cells (cells that line blood vessels) and supportive cells. When tissues are injured, the vascular niche endothelial cells direct the stem cells, via angiocrine factor expression, to repair and restore the damaged tissue. This restorative capacity is most active during childhood and youth but starts to diminish with increasing age. HDT provided to eradicate cancer cells also cause diffuse, collateral damage to vascular niches of multiple healthy organs. In particular, the organs with the highest cell turnover (ones with most active vascular niches) are severely affected. Specifically, the oral-GI tract, dependent on constant renewal of its mucosal lining, starts to break down upon vascular niche injury. The mucosal breakdown can cause severe nausea, vomiting and diarrhea. In addition, the bacteria in the gut may escape into the circulation, resulting in patients becoming ill with endotoxemia, bacteremia or potentially lethal sepsis. HDT-related vascular niche damage can also occur in other organs resulting in severe or life-threatening complications involving the lung, heart, kidney, or the liver. Collectively, these complications are known as severe regimen-related toxicities or SRRT. SRRT can occur as frequently as 50% in lymphoma HDT-AHCT patients, with increased rate and severity in older patients.

About AB-205

AB-205 is a first-in-class engineered cell therapy consisting of proprietary 'universal' E-CEL (*human **e**ngineered **c**ord **e**ndothe**l**ial*) cells. The AB-205 cells are intravenously administered after the completion of HDT on the same day as when the patient's own (autologous) blood stem cells are infused. AB-205 acts promptly to repair injured vascular niches of organs damaged by HDT. By repairing the vascular niches, AB-205 restores the natural process of tissue renewal, vital for organs such as oral-GI tract and the bone marrow. Successful and prompt organ restoration can prevent or reduce SRRT, an outcome that is beneficial to quality of life and cost reductive to the healthcare system.

About CIRM

The California Institute for Regenerative Medicine (CIRM) was established in November, 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure provided $3 billion in funding for California universities and research institutions. With over 300 active stem cell programs in their portfolio, CIRM is the world's largest institution dedicated to stem cell research. For more information, visit www.cirm.ca.gov.

About Angiocrine Bioscience Inc.

Angiocrine Bioscience is a clinical-stage biotechnology company developing a new and unique approach to treating serious medical conditions associated with the loss of the natural healing and regenerative capacity of the body. Based on its novel and proprietary E-CEL® platform, Angiocrine is developing multiple therapies to address unmet medical needs in hematologic, musculoskeletal, gastrointestinal, soft-tissue, and degenerative/aging-related diseases. A Phase 3 registration trial is being planned for the intravenous formulation of AB-205 for the prevention of severe complications in lymphoma patients undergoing curative HDT-AHCT. This AB-205 indication is covered by the Orphan Drug Designation recently granted by the US FDA. In addition, Angiocrine is conducting clinical trials of local AB-205 injections for the treatment of: (1) rotator cuff tear in conjunction with arthroscopic repair; and, (2) non-healing perianal fistulas in post-radiation cancer patients.

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