BryoLogyx Announces Cooperative Research and Development Agreement for Bryostatin-1 With National Cancer Institute

August 04, 2020 09:30 AM Eastern Daylight Time

DANVILLE, Calif.--(BUSINESS WIRE)--BryoLogyx, Inc. today announced that it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), to conduct a Phase I clinical trial with bryostatin-1 in pediatric and young adult patients with relapsing or refractory CD22 expressing acute lymphoblastic leukemia (ALL) and lymphoma. The study, expected to start later this year, will be the first in patients to evaluate the ability of bryostatin-1 to upregulate expression of CD22, a cancer immunotherapy target often downregulated following antibody drug conjugate or CAR T adoptive therapies. The Company is planning future clinical trials with bryostatin-1 to evaluate its ability to upregulate other antigen targets associated with B cell hematological malignancies.

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"This CRADA provides an accelerated path to demonstrating clinical proof-of-concept for our innovative approach that enhancing the response to cancer immunotherapy can be achieved by increasing expression of antigen targets," said Thomas M. Loarie, CEO of BryoLogyx. "Our collaboration builds on NCI's pioneering work showing that relapse in patients undergoing ALL treatment with a CD22-directed CAR T therapy is associated with reduced CD22 antigen expression; and that in preclinical studies, bryostatin-1 upregulates CD22 density on the cancer cell, improves CAR T functionality, duration of response, and survival in CAR T-treated human xenograft models."

Under the CRADA, NCI researchers will test bryostatin-1 to evaluate its ability to modulate CD22 in patients with relapsed/refractory CD22+ ALL and lymphoma, while specifically evaluating its safety, defining the optimal biologic dose required to lead to an increase in CD22 site density, and anti-leukemic properties.

Mr. Loarie noted that BryoLogyx plans to follow this CRADA study with additional trials to expand the understanding of how bryostatin-1 increases tumor antigen expression and amplifies the immune response to several immune-oncology therapies in a variety of hematologic cancers.

The CRADA follows recent agreements entered into by BryoLogyx with Neurotrope to acquire a preclinical data package for a BryoLogyx-sponsored IND, along with study drug for the clinical trial.

About BryoLogyx

BryoLogyx is developing a new class of drugs to enhance the response rates and treatment durability of cancer immunotherapies and anti-HIV agents. The company's initial focus is on cancer, where it capitalizing on two recent scientific advances: the discovery that a complex natural product, bryostatin, stimulates tumor antigen production to amplify the immune response unleashed by cancer immunotherapy; and the invention of the first practical synthetic production method for bryostatin and analogs, enabling their availability for commercial development. BryoLogyx has exclusive rights from Stanford University to the method's use in the areas of cancer and HIV. Bryostatin, currently in development for use with immuno-oncology agents, has an established safety profile based on clinical studies involving more than 1100 patients. Learn more at www.bryologyx.com

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