biosplice

PRESS RELEASE

First Subject Dosed in Biosplice Therapeutics Phase 1b Clinical Trial in Oncology

This trial will evaluate the clinical safety and efficacy of orally administered cirtuvivint (SM08502) in multiple combination cohorts

SAN DIEGO – November 17, 2021 - Biosplice Therapeutics, Inc. ("Biosplice"), a clinical-stage biotechnology company pioneering therapeutics based on CLK/DYRK kinase modulation for major diseases, announced the dosing of the first subject in a Phase 1b, open-label, multi-center, dose-escalation, dose expansion clinical trial of cirtuvivint in subjects with advanced solid tumors. Several standard-of-care agents are being tested in combination with cirtuvivint in diseases including castration resistant prostate cancer (CRPC), non-small cell lung cancer (NSCLC), and colorectal cancer (CRC). Many patients with these types of cancers progress on earlier line treatments, and these patients critically need new combination agents that improve response rates or extend the duration of response for late-stage cancer patients.

This clinical trial (NCT05084859) will evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor efficacy of cirtuvivint administered orally once daily following a five days on, two days off treatment schedule in combination with chemotherapy or hormonal therapy.

Darrin Beaupre, MD, PhD, Chief Medical Officer, Oncology, of Biosplice, commented, "We are excited to broaden our investigation of cirtuvivint, our first-in-class CLK/DYRK inhibitor in combination studies. We have rationally selected CRPC, NSCLC and CRC based on a large body of non-clinical evidence which suggests that cirtuvivint will be active in these tumors. In addition, pre-clinical and published data support the combinations chosen and we have biomarkers for each of the three diseases that may be predictive of response."

Biosplice also has been evaluating the safety and pharmacokinetics of orally administered cirtuvivint in subjects with advanced solid tumors in its first in human Phase 1 clinical trial (NCT03355066), with an estimated completion date of December 2022.

About Cirtuvivint (SM08502)
Cirtuvivint is a small-molecule inhibitor of the CDC-like kinases (CLK) and Dual-specificity tyrosine phosphorylation-regulated (DYRK) kinases that are emerging as key contributors to numerous forms of cancer. Cirtuvivint's primary mechanism of action, inhibition of CLK and DYRK kinases, has the potential to attenuate the expression of genes critical to growth, survival, and drug resistance through disruption of alternative pre-mRNA splicing. Cirtuvivint is in development for the treatment of advanced solid tumors.

About Biosplice
Biosplice is pioneering first-in-class, small-molecule therapeutics based on CLK/DYRK kinase modulation. Stemming from foundational discoveries in Wnt pathway modulation, Biosplice has elucidated novel biology linking CLK/DYRK kinases to the therapeutic regulation of alternative

pre-mRNA splicing, as well as other biological mechanisms with significant therapeutic potential. Alternative splicing is an essential biological process that regulates the diversification of proteins in a cell, which, in turn, determines cell type and function. Biosplice's target class governs the selection of tissue-specific pre-mRNA splice sites, making these kinases attractive, druggable targets within the cellular "command and control" center. Biosplice's drugs in clinical development include lorecivivint for osteoarthritis (in Phase 3), cirtuvivint for numerous cancers, and a broad pipeline that ranges from Alzheimer's disease to other degenerative conditions. Learn more at https://www.biosplice.com.

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