

**PRESS RELEASE**

**Biosplice Therapeutics Announced New Clinical Data for Cirtuvivint (SM08502)  
at the European Society for Medical Oncology Meeting**

*Results showed evidence of clinical activity for cirtuvivint in advanced cancer patients.*

**SAN DIEGO – Sept 10, 2022** – Biosplice Therapeutics, Inc. (“Biosplice”), a clinical-stage biotechnology company pioneering therapeutics based on CLK/DYRK kinase modulation for major diseases, announced today the presentation of new clinical data for cirtuvivint (SM08502), its first-in-class small-molecule CLK/DYRK inhibitor. The oral presentation was delivered in Paris, France at the 2022 European Society for Medical Oncology (ESMO) meeting. With evidence of clinical benefit, cirtuvivint is currently progressing through two Phase 1 trials as a drug candidate for the treatment of advanced solid tumors. In addition, Biosplice is developing next-generation, highly-selective drug candidates within its CLK/DYRK target class for a broader array of cancers, including liquid tumors.

The oral presentation, entitled “Preliminary evidence of clinical activity from Phase 1 and 1b trials of the CLK/DYRK inhibitor cirtuvivint (CIRT) in subjects with advanced solid tumors,” was delivered by Dr. Aaron Scott, MD from the University of Arizona Cancer Center. The first-in-human Phase 1 study evaluated the pharmacokinetics, pharmacodynamics, safety, and efficacy of cirtuvivint in subjects with advanced solid tumors while the Phase 1b study combined cirtuvivint with standard-of-care agents in castrate-resistance prostate cancer, colorectal cancer, and non-small cell lung cancer. Preliminary results from the cirtuvivint dose escalation in these two studies provided early evidence of clinical activity with a manageable safety profile in a heavily pre-treated advanced cancer patient population. In addition, the preliminary data from the combination trial suggested that in castrate-resistance prostate cancer, hormonal therapy resistance may be overcome when cirtuvivint is combined with abiraterone acetate.

“We are enthusiastic about the promising early clinical activity observed with our first in class CLK/DYRK inhibitor cirtuvivint in this difficult-to-treat Phase 1 cancer patient population,” said Darrin Beaupre, M.D., PhD, Chief Medical Officer in Oncology at Biosplice Therapeutics.

“Alternative splicing has been reported to be a driver for many of the hallmarks of cancer, including growth, survival, and drug resistance; the spliceosome itself has been identified as therapeutic vulnerability in a number of solid and liquid tumors. We are pleased to be making progress in exploiting this vulnerability with cirtuvivint”.

A copy of the presentation materials can be seen on the [Publications](#) page of the Biosplice Therapeutics website.

**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

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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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