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PRESS RELEASE

Biosplice Publishes Successful Clinical Trial in Knee Osteoarthritis

Biosplice's Phase 2b trial for lorecivivint hits primary endpoint in osteoarthritis pain

SAN DIEGO – April 26, 2021 – Biosplice Therapeutics, Inc. ("Biosplice"), a clinical-stage biotechnology company pioneering therapeutics based on alternative pre-mRNA splicing for major diseases, announced today the publication of its successful Phase 2b knee osteoarthritis clinical trial data in *Osteoarthritis and Cartilage*. In this 24-week clinical trial, Biosplice's groundbreaking knee OA drug candidate, lorecivivint, met primary endpoints of Pain NRS (daily pain measurement) at both 12 and 24-week timepoints. As in previous trials, lorecivivint appeared safe and well tolerated.

"Healthcare professionals need an approach for treating knee osteoarthritis that can provide durable pain relief, improve functionality, and be safely utilized over a long period of time," said Biosplice Chief Medical Officer, Yusuf Yazici, MD. "Biosplice aims to provide physicians a knee osteoarthritis treatment that does not compromise between efficacy and safety. This local, intra-articular injection would provide a much-needed, potentially disease-modifying treatment option to physicians and patients alike."

Biosplice is currently conducting two Phase 3 trials for lorecivivint, STRIDES-1 and STRIDES-X-ray, which are expected to unblind in the second half of 2021. These confirmatory Phase 3 clinical trials (NCT04385303 and NCT03928184) are further evaluating the impact of lorecivivint on knee osteoarthritis pain, function, and structure and have been modeled after Biosplice's successful Phase 2b from the standpoint of their primary endpoints of daily pain score at three months.

"The FDA has made clear in its public guidance that any approvable therapy for osteoarthritis must show clinical symptom benefit," commented Mark Fineman, SVP of Clinical Affairs at Biosplice. "Our Phase 3 trials measure pain at three months as primary endpoints, like our successful Phase 2b trial, while benefitting further in statistical power from an enrollment of over twice the number of patients per arm. We are also measuring structural and functional improvements as key secondary endpoints and evidence of disease modification."

As mentioned in the paper titled A Phase 2b Randomized Trial of Lorecivivint, a Novel Intra-articular CLK2/DYRK1A Inhibitor and Wnt Pathway Modulator for Knee Osteoarthritis, in this 24-week clinical trial, lorecivivint showed clinically meaningful and statistically significant improvements in pain and function compared with placebo in subjects with knee osteoarthritis.

About Biosplice

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Biosplice is developing first-in-class, small-molecule therapeutics based on pioneering science of alternative pre-mRNA splicing. Stemming from foundational discoveries in Wnt pathway modulation, Biosplice has elucidated novel biology linking CLK/DYRK kinases to the therapeutic regulation of alternative splicing. Alternative splicing is an essential biological mechanism 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 mRNA splice sites, making them 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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