



## **Symic Bio Completes the MODIFY2 Phase 2 Trial of SB-061 for the Treatment of Knee Osteoarthritis**

*– MODIFY2 study evaluated safety and efficacy in pain management for patients with mild-to-moderate osteoarthritis of the knee –*

**SAN FRANCISCO, Feb. 7, 2018** – Symbic Bio, a biopharmaceutical company developing novel extracellular matrix targeting drugs, today announced topline results from the MODIFY2 Phase 2 clinical trial of SB-061 for symptom management in mild-to-moderate osteoarthritis of the knee. The 12-week, multicenter, double-blind trial of 60 patients was designed to investigate the effects of SB-061 in the overall population as well as a prespecified subpopulation of patients with knee effusions. MODIFY2 demonstrated that treatment with SB-061 was well-tolerated, with a safety profile consistent with the saline control treatment group. In patients with knee effusions, measurements of reduction in pain from baseline at 4 weeks by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain while walking score (WOMAC A1), were consistent with SB-061 treatment providing a clinically relevant degree of improvement compared to the control group, although these observations did not reach the threshold of statistical significance as the trial was designed with a small sample size.

In patients with knee effusions, the repeated measures analysis of pain reduction over 4 weeks and repeated measures analysis of pain reduction over 12 weeks were consistent with an effect of SB-061 in potentially providing a clinically meaningful degree of improvement relative to control. These observations of a potential treatment effect were maintained in the WOMAC pain and function sub-scores as well as the full WOMAC. In the overall patient population including patients with and without effusions, treatment with SB-061 did not meet the primary endpoint of demonstrating a clinically meaningful improvement compared to control.

"We are encouraged by the performance of SB-061 in the clinic thus far, especially the data in patients with effusions," said Nathan Bachtell, M.D., Chief Medical Officer of Symbic Bio. "These results build upon previously announced Phase 1/2a results from the MODIFY-OA trial that supported the safety, tolerability and intended mechanism of action of SB-061. Given the biomarker results and efficacy signal seen in subjects with knee effusions in the MODIFY-OA trial, a specific cohort from this patient population which is known to have more active inflammation in the joint, the MODIFY2 trial was designated *a priori* to analyze this patient subset. The MODIFY2 results support that patients with effusions have a clinically meaningful response to SB-061 that can be confirmed in a study focused on patients in this population. We expect to provide additional detail at an upcoming medical conference."

"Targeting a subset of osteoarthritis patients with active inflammation, as evidenced by the presence of an effusion, together with the multifaceted anti-inflammatory properties SB-061, reflects the coming trend in osteoarthritis development given the heterogeneity in the osteoarthritis population," commented Ali Guermazi, M.D., Ph.D., Professor of Musculoskeletal Radiology and Vice Chair of Academic Affairs at Boston University School of Medicine. "Given the signal in the MODIFY2 trial,

targeting a subpopulation with effusions reflects a personalized approach to successful clinical development.”

“Ongoing development of SB-061 as an agent that can modify both the symptoms and disease progression of osteoarthritis will focus on patients with knee effusions, which constitutes more than 50 percent of those diagnosed with osteoarthritis of the knee,” commented Ken Horne, Chief Executive Officer of Symic Bio. “Targeting patients with active synovial inflammation represents a novel approach to enriching a trial population, a strategy that we expect to contribute to effective clinical development. We are currently planning a Phase 2b trial of SB-061 for these patients, which we expect to initiate this year.”

Additional information on the design of SB-061 for the treatment of osteoarthritis can be found at [www.symic.bio/pipeline/osteoarthritis](http://www.symic.bio/pipeline/osteoarthritis).

### **SB-061 from Symic Bio**

Osteoarthritis is a chronic inflammatory disease effecting approximately 10 percent of the U.S. population.<sup>1</sup> Of these patients, approximately 50 percent have evidence of an accumulation of fluid in the affected joint, known as an effusion, as a result of active inflammation.<sup>2</sup> SB-061, a therapeutic bioconjugate molecule inspired by the properties of aggrecan, is a drug delivered directly to the joint via intra-articular injection. SB-061 is designed to directly target the extracellular matrix within the joint cavity and inhibit degradation, halting the matrix-induced inflammatory cycle that drives the symptoms and progression of osteoarthritis. The goal of this approach is to both modify the course of disease by reducing joint degradation and to decrease symptoms due to inflammation. SB-061 is in clinical development for patients with osteoarthritis of the knee with effusions.

1. Murphy L., and Helmick, C.G. *American Journal of Nursing*. 2012 March;112(3 Suppl 1):S13-9
2. Maricar, N. *et al.*, *Seminars in Arthritis & Rheumatism*. 2016 April;45(5):556-63.

### **About Symic Bio**

Symic Bio is a biopharmaceutical company developing novel matrix regulators, a new category of therapeutics focused on matrix biology. These therapeutics, with potential applications in a wide variety of disease states, are inspired by naturally occurring macromolecules that play key regulatory roles within the extracellular matrix. Symic Bio currently has two clinical candidates: SB-061, directed at disease modification and pain management in the treatment of osteoarthritis, and SB-030, targeting the prevention of peripheral vein graft failure. In addition, Symic Bio is investigating applications in the areas of fibrosis, oncology and diseases of the central nervous system. For additional information please visit the company’s website at [www.symic.bio](http://www.symic.bio), LinkedIn page at [www.linkedin.com/company/symic-bio](http://www.linkedin.com/company/symic-bio) or follow on Twitter at [www.twitter.com/symicbio](http://www.twitter.com/symicbio).

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