Symic Bio Announces 12-Month Results from the SHIELD Trial of SB-030 in Peripheral Vascular Disease

– Data from 12-month follow-up demonstrates statistically significant improvement in clinical efficacy outcome –

– Trial of SB-030 in prevention of vein graft failure in patients with advanced peripheral vascular disease planned to begin in the second half of 2018 –

SAN FRANCISCO, April 2, 2018 – Symic Bio, a biopharmaceutical company developing novel matrix-targeting biotherapeutics, today announced 12-month results from the Phase 1/2 SHIELD trial evaluating SB-030 in patients with peripheral vascular disease undergoing angioplasty. Under an extended trial protocol allowing assessment of secondary endpoint measurements at 12 months following intervention, patients in the treatment group demonstrated a clinically meaningful and statistically significant 23 percent reduction in index limb re-intervention as compared with the control group (p=0.025). This result is consistent with a previously-announced trend observed at six months following intervention. Treatment with SB-030 demonstrated no clinically meaningful difference in adverse events or serious adverse events compared to control, supporting the safety profile observed at six months following intervention.

“Reduction of the need for re-intervention provides support for the potential of SB-030 to improve outcomes in vascular procedures,” commented Andrew Holden, MBChB, director of interventional radiology at the Auckland Regional Public Health Service and one of the lead investigators in the SHIELD trial. “It is encouraging to see results at 12 months that support observations at 6 months, demonstrating long-term durability of the effects of SB-030 as well as long-term safety. This extended effect provides additional support of the unique mechanism of action and its potential to impact clinical practice.”

“The durable results of SB-030 in angioplasty compare favorably with the effects of other treatments in clinical practice and offer additional benefits in safety,” stated Nathan Bachtell, M.D., Chief Medical Officer of Symic Bio. “Because of its unique mechanism of action and demonstrated effects, SB-030 represents an attractive potential solution in other areas of vascular interventions, including reducing the risk of graft failure following peripheral artery bypass surgery. Given the safety and efficacy of SB-030 demonstrated to date and the lack of treatment options for patients at risk of vein graft failure, Symic plans to target this unmet medical need in subsequent clinical trials. The next clinical trial is expected to begin in the second half of 2018.”

A Phase 2 trial evaluating the potential for SB-030 to prevent graft failure under a U.S. Investigational New Drug (IND) protocol is in the planning stage.
About SB-030

SB-030 is in development to improve clinical outcomes following peripheral vein graft procedures. SB-030 is administered locally, acting on the extracellular matrix of exposed connective tissue. In targeting responses mediated by the extracellular matrix, SB-030 aims to reduce the scarring (neointimal hyperplasia) and blood clot formation that leads to vein graft failure. Beyond vein graft failure, SB-030 has potential applications for other types of vascular procedures, including coronary bypass and surgical intervention in late-stage kidney disease. For more information on SB-030 please see http://www.symic.bio/pipeline/vascular-disease/ or https://www.youtube.com/watch?v=deyho7VBXTw.

About the SHIELD trial

The proof-of-concept Phase 1/2 SHIELD (Study in Humans to Investigate the Efficacy and Safety of Luminal SB-030 Delivery in Peripheral Vascular Disease) trial was a parallel, blinded, randomized (2:1) clinical trial undertaken at multiple sites in Australia and New Zealand. The trial enrolled 67 patients with symptomatic peripheral vascular disease. It compared the safety and efficacy of balloon angioplasty with or without the administration of SB-030 (also known as SBVC) in patients undergoing angioplasty to address reduced blood flow (occlusions) within the femoropopliteal artery. The trial included a primary efficacy measurement of late lumen loss at 6 months, a standard measure of restenosis following vascular injury, and evaluated other clinically relevant outcomes such as target lesion revascularization. More information on the trial can be found at https://clinicaltrials.gov/ct2/show/NCT02568293.

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, LinkedIn page at www.linkedin.com/company/symic-bio or follow on Twitter at www.twitter.com/symicbio.

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