

Safi Biotherapeutics and ARMI | BioFabUSA Initiate Collaboration to Support Large-Scale Development of mRBCs

Partnership focused on transitioning Safi manufactured human red blood cells (mRBCs) to cGMP manufacturing at a clinically meaningful scale

CAMBRIDGE, MA, UNITED STATES, February 10, 2025 /EINPresswire.com/ -- Safi Biotherapeutics, a biotech company producing stem-cell derived, manufactured human red blood cell (mRBC) products for civilian and military transfusion needs, and ARMI | BioFabUSA, a non-profit organization and Department of Defense Manufacturing Innovation Institute, today announced a collaboration



focused on the manufacturing of Safi's mRBCs to support regulatory requirements and initial clinical studies.

"We are very excited to launch this collaboration with ARMI | BioFabUSA. This is a critical step toward manufacturing our mRBCs at a clinically meaningful scale, as well as moving our product down the regulatory path toward an IND submission," said Doug McConnell, Chief Executive Officer and Co-Founder of Safi Biotherapeutics. "We are initially focused on bringing mRBCs to patients in transfusion indications ranging from trauma to sickle cell disease, where there is a high unmet need for an appropriately matched, on-demand supply of RBC units to help these patients."

The partnership will support Safi's mRBC process development at large scale, an early critical step in improving mRBC commercial viability. Safi, headquartered in Cambridge, Mass., anticipates growing its initial U.S. presence near ARMI | BioFabUSA's campus in Manchester, New Hampshire, adjacent to essential facilities and interdisciplinary expertise.

McConnell continues, "BioFabUSA provides us with increased manufacturing capabilities, enabling us to transfer our mRBC process into cGMP-ready conditions to develop an acute transfusion mRBC product to help address shortfalls in both military and civilian supply."



Safi is excited to launch our collaboration with ARMI | BioFabUSA, a critical step toward manufacturing our mRBCs at a clinically meaningful scale and moving down the regulatory path to IND submission"

Safi CEO and Co-Founder Doug McConnell

"Safi Biotherapeutics is a pioneering leader in the high-efficiency production of mRBCs for transfusion needs, and we enthusiastically support its efforts to address ongoing critical shortages in the U.S. and international military and civilian blood supply, including military traumatic injury transfusion needs and the access and alloimmunization challenges faced by patients living with sickle cell anemia, cancer, and other conditions," said Jennifer MacDonald, MD, Chief Operating Officer of ARMI | BioFabUSA. "We look forward to working with Safi to advance a scalable, consistent, cost-effective approach to the manufacture of bioengineered blood products that enables these life-

saving technologies to reach every service member and civilian who needs them."

About Safi Biotherapeutics

Safi Biotherapeutics produces stem-cell derived, human RBCs with the goal of providing a highly characterized cell therapy product at industrial scale and viable economics for civilian and military transfusion needs. Safi's manufacturing blueprint for RBC production is the most advanced in the industry, and the company's readily addressable markets include chronic transfusion indications such as sickle-cell disease and acute transfusion settings such as civilian and military hospitals during critical times of need. Safi leadership, comprised of industry and cell therapy veterans from DARPA, Vertex Pharmaceuticals, and Loughborough University in the United Kingdom, launched the company in 2020 as part of the U.S. Department of Defense On-Demand Blood program.

For more information on Safi, visit: https://safi.bio/ or follow us on LinkedIn.

About ARMI | BioFabUSA

The Advanced Regenerative Manufacturing Institute (ARMI) I BioFabUSA is a Member-based non-profit organization and U.S. Department of Defense Manufacturing Innovation Institute devoted to advancing the U.S. bioeconomy. ARMI I BioFabUSA's mission is to develop a highly competitive, capable and innovative domestic cell, tissue and organ manufacturing ecosystem that will fundamentally transform healthcare for chronic illness and traumatic injury; and to build the trained and ready workforce essential for that ecosystem. With an unwavering focus on innovation and impact, the Institute and its nearly 200 Members nationwide are bringing together expertise in biochemistry, medicine, engineering, and biomanufacturing to accelerate and de-risk the development of groundbreaking regenerative therapies that will save lives and impact military and public health.

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