



Press Release
Media Contacts:
IB Communications
Tel +44 (0)20 89434685
germfree@ibcomms.agency

GermFree and Caring Cross partner to transform access to cellular gene therapies

Innovative collaboration aims to democratize life-saving CAR-T and stem cell gene therapies

Ormond Beach, Fla. and Gaithersburg, Md., August 21, 2024 – GermFree, a pioneering leader in modular cleanroom infrastructure and services, and Caring Cross, a forward-thinking 501(c)(3) nonprofit committed to accelerating the development of advanced medicines and ensuring patient access to transformative therapies, today announced a new partnership to transform access to cell and gene therapies (CGTs). The collaboration is set to make cellular gene therapies more available to patients by creating a decentralized, point-of-care manufacturing model that combines GermFree’s cutting-edge mobile cleanroom units with Caring Cross’s innovative manufacturing technologies and pipeline of cellular gene therapy products.

Most CGTs are one-and-done therapies made by modifying a patient’s own cells, which have been widely approved to treat – and often cure – patients with intractable diseases like late-stage blood cancers, as well as undertreated chronic diseases like sickle cell disease. Despite its best efforts, the biopharma industry has been unable to reach all eligible patients because of the way the drugs are made. Until now, they have been too expensive, take too long to manufacture, and were only available to patients in affluent regions.*

The partnership between GermFree and Caring Cross builds on three years of preparation, including a pilot project with Brazil’s Fundação Oswaldo Cruz (Fiocruz) to launch local CAR-T manufacturing next year. GermFree will lead the facility innovation, providing advanced hardware and digital platforms to ensure robust quality control. Meanwhile, Caring Cross will develop the therapeutic product, provide the workflows and manufacturing protocols, and train doctors and healthcare organizations in the production of these therapies.

By leveraging these capabilities, the partnership will create a comprehensive, end-to-end solution for point-of-care manufacturing of CAR-T and other cellular gene therapies.

“We are focused on making these transformative therapies more accessible by manufacturing CGT products at the point-of-care, near or at clinical centers where patients receive treatment,” said Boro Dropulić, Executive Director and co-founder of Caring Cross. “With a modest investment, clinical centers and affiliated organizations can leverage their existing capabilities to produce CAR-T and other CGT products sustainably and affordably. Our goal is to empower these centers to provide life-saving therapies at a fraction of the current cost.”

By leveraging a point-of-care manufacturing model, GermFree and Caring Cross are poised to make cellular gene therapies available in remote and underserved locations, bridging gaps in current industry capabilities.

“This is a transformational moment for the field, where sustainable models that have long been theoretical will finally begin to impact patients,” said Carol Houts, Chief Strategy Officer at GermFree. “We often hear that innovation leads to affordability, but patients have been suffering while they wait. The technology for mobile cleanrooms with stringent quality management systems is ready. This partnership aims to inspire the industry to advance and demonstrate that CAR-T and other cell therapies can be made accessible globally, regardless of regional wealth disparities.”

A network of organizations dedicated to advancing point-of-care manufacturing, regulatory approval, and product provision is essential to creating equitable, affordable, and sustainable cures worldwide. To learn more about partnering with GermFree and Caring Cross, visit www.germfree.com and www.caringcross.org.

About GermFree

GermFree is a global leader in the design, manufacture, and maintenance of modular cleanroom environments. With decades of global expertise in serving the biopharmaceutical industry, GermFree specializes in providing advanced solutions that enhance the safety, efficiency, and sustainability of critical healthcare manufacturing processes. GermFree is continuing to invest in cleanroom design and manufacturing solutions and is committed to providing innovative solutions, with the goal of improving patient access to critical medicines. GermFree is backed by the healthcare growth equity investor, EW Healthcare Partners. www.germfree.com

About Caring Cross

Caring Cross is a 501(c)(3) nonprofit dedicated to accelerating the development of advanced medicines and ensuring access to cures for all patients, everywhere. To enable its mission, Caring Cross is developing technologies and therapeutic candidates to improve the accessibility, affordability, and applicability of advanced medicines like CAR-T therapy and stem cell gene therapy. Caring Cross founded Vector BioMed, a for-profit vector contract development and manufacturing organization (CDMO), specializing in rapid lentiviral vector manufacturing solutions, to provide the industry a source of affordable high-quality GMP Lentiviral vectors. For more information on Caring Cross visit <https://caringcross.org/>. For more information on Vector BioMed visit <https://vectorbiomed.com/>.

*** GermFree and Caring Cross: Addressing Critical Barriers to Access**

GermFree and Caring Cross are partnering to tackle the three biggest obstacles preventing patients from accessing these life-saving therapies: cost, geography, and time.

Cost: The current cost of CAR-T cell therapies starts at \$350,000, with some patient-specific therapies exceeding \$3 million. Not only does this put them out of reach for many today, it is difficult to imagine how any health system in the world could sustainably afford these therapies for all the patients who need them – particularly as the field expands into new indications.

GermFree and Caring Cross aim to significantly reduce these costs by developing a point-of-care manufacturing model and partnering directly with local governments and institutions. This can lead to fewer expensive steps and opportunities for waste, making these therapies less expensive and more accessible to patients. In addition, Caring Cross's mission as a non-profit is to leverage its decades of CAR-T development experience to create affordable therapies.

Geography: To get access today, patients need to reach a specialized facility for blood collection, before it can be shipped to a laboratory – often crossing international borders – where it undergoes the complex process of being transformed into the final CAR-T cell product. After the transformation, the finished CAR-T cell product must be transported back to one of a relatively small number of clinical environments for infusion into the patient.

This process is highly complex, requiring multiple transfers and stringent regulatory compliance at each stage. By enabling the entire manufacturing process nearer to any patient's location, the mobile cleanrooms will allow local teams to make the therapies, with the potential to skip steps like cryopreservation and long-distance cold-chain shipping. This reduces the likelihood of delays, damage, or degradation of the cells, while empowering local medical staff all over the world.

Time: The extensive logistics involved can keep patients away from their homes and families for an unacceptably long period, further complicating their treatment journey and adding emotional and financial stress. Indeed, some patients have died on waiting lists to get the therapy, while others have been too sick to even endure the wait.

Shortening the "vein-to-vein time" – the period from when blood leaves a patient to when a therapy is given – is crucial for the effectiveness of these therapies, which have shown remarkable results in treating late-stage blood cancers and other intractable diseases. The collaboration will focus on minimizing the time from initial blood collection to the final infusion, enhancing treatment outcomes.