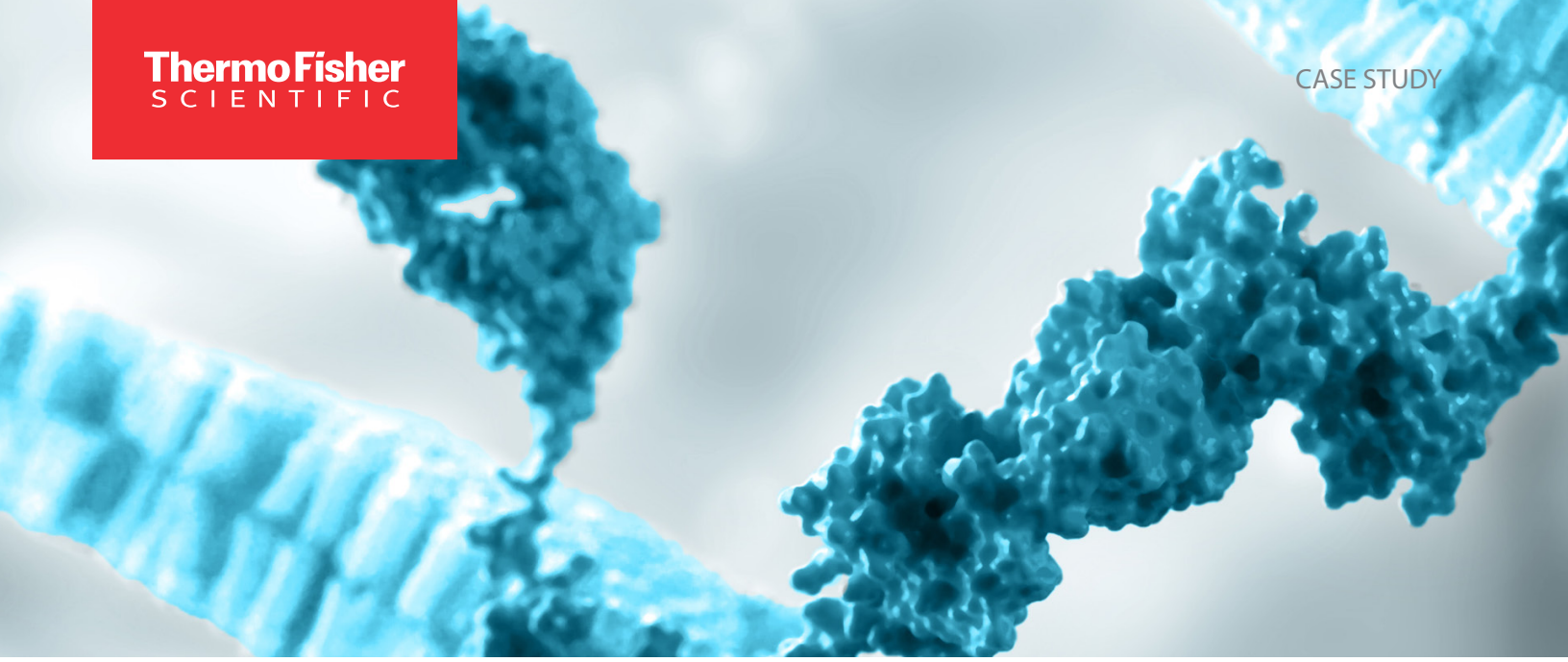
ThermoFisher SCIENTIFIC

CASE STUDY



ATMP Fast Track: From clinical to commercial

Introduction

A leading allogeneic T-cell immunotherapy company pioneering the development of transformative therapies for patients with serious diseases including solid tumors, hematologic cancers, and autoimmune diseases needed expertise and help ushering the innovative therapy from academia through to commercialization.

In contrast to autologous T-cell therapy in which patients donate their own blood cells for development of the treatment, allogeneic T-cell therapy obtains cells from healthy donors. The cells from these individuals are ultimately transduced with a receptor gene that allows for specific targeting of cancer cell antigens. The cells are then provided to a patient via transfusion in hopes that the donor cells will replicate and destroy the cancer cells.

Because this company is relatively small, it sought a partner that could support its phase III global study and help move the therapy through to the commercial phase. Success of this therapy would address a significant unmet need for patients who fail currently available treatment options.

Situation

The company's phase III registration-enabling study assessed the efficacy and safety of its new product. The global nature of the study presented a set of unique challenges, including the need for batch reviews in the US, UK, and mainland Europe, which required a strong understanding of country-specific regulations (including Brexit-related changes in regulations) and the ability to comply with them under very tight timelines.

An additional challenge was the need for speed. Turnaround time to patients is of utmost importance with advanced therapy medicinal products (ATMPs). These customized therapies generally require that cells be collected from the patient and the medication be manufactured and returned within just a few days. **Many patients receiving ATMPs are in a critical state and facing their last opportunity for care. The timing of manufacture or delivery of supplies to the patient must be calculated and executed with precision.**

Finally, ATMP manufacturing is a very dynamic process that requires patient-specific packing and labeling, just-in-time or late-stage customization, qualified person (QP) release according to country rules, and specialized, white-glove delivery. In a niche market with such a significant impact to patients, there was no room for error.

For these reasons, the company needed a partner that could offer global expertise and reliable services to ensure that quality was maintained, regulations were followed, and patients received their medication on time. Clear and transparent communication and strong collaboration between teams were also critical to maintain the integrity of the entire project.

Solution

The company had a previous working relationship with Thermo Fisher Scientific in a more limited capacity and decided that the CDMO's reliability in early-phase projects, scale-up capabilities, and global expertise would be well suited to this project.

As part of the new partnership, Thermo Fisher was able to help manage the company's phase III study in two different locations thanks to its deep experience across global markets. The CDMO's familiarity with the Brexit-specific changes to clinical trial regulations and ability to provide QP resources and regulatory support in Europe enabled the company's team to manage logistics across multiple countries without delays.

Thermo Fisher also provided temperature management throughout the clinical supply chain (receipt, storage, packaging, labeling, and distribution). Over time, it also scaled up manufacturing and provided just-in-time services with quick release of single shipments of two doses: one for immediate use and one for next dose use.

Results

The clinical supply-to-commercial partnership between Thermo Fisher and this leading allogeneic T-cell immunotherapy company enabled the successful importation and release of the company's product for hundreds of patients. When the product is commercially released, thousands of patients will have the opportunity to receive the company's allogeneic T-cell therapy. Thermo Fisher achieved on-time in-full delivery (OTIF) of 99%, delivering orders to patients in five days or less, regardless of patient location.

During the course of the clinical trial, the company also worked with Thermo Fisher on its commercial filing and audit schedule in preparation for adding an additional partner. Under this new arrangement, the company will remain as the manufacturer, Thermo Fisher will remain as the service provider, and a third company will bring the therapy to market. The EMA's Committee for Medicinal Products for Human Use (CHMP) granted accelerated assessment approval for the product and an EU approval decision was made in 2022.

Summary

A leading allogeneic T-cell immunotherapy company needed a partner that could navigate the various global regulatory requirements and tight timelines of its phase III clinical trial and support its efforts toward commercialization. The company's end-to-end collaboration with Thermo Fisher allowed for the successful distribution of its clinical supply, and its continued partnership through commercialization will provide thousands of patients with the opportunity to try an innovative and potentially life-changing therapy.

To learn more about how Thermo Fisher can help support your drug delivery project, contact us.

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