NAVIGATING THE SUPPLY CHAIN FOR ADVANCED THERAPIES

Fisher BioServices
A Thermo Fisher Scientific Brand

SUPPLY CHAIN & LOGISTICS HUB

Situation

This collaborative case study with Fisher BioServices and SOTIO describes the use of dispersed storage and cold chain logistics, around a central manufacturing facility to create a cost efficient and robust supply chain.

SOTIO is currently conducting a VIABLE trial, which is a randomized, double-blind, multi-centre parallel-group Phase III study. It is designed to assess the efficacy and safety of the ACI in combination with standard of care in comparison with placebo and standard of care in men with metastatic castration-resistant prostate cancer eligible for first line chemotherapy.

For the supply chain, this means management of time critical, temperature controlled shipments to and from more than 20 EU and non-EU countries and the treatment of over 1000 patients. To maximize efficiency, SOTIO pursued a single manufacturing site strategy that has the capacity to manufacture all of its global clinical trial needs. The inbound cellular supply chain is leukapheresis at 15-25°C, with a 30-hour shelf life. The outbound cellular supply chain uses cryogenic storage hubs and distribution.

In addition, there is a critical consumable supply chain that needs to ensure that donation and treatment kits, as well as the secondary packaging and labelling systems, operate in synergy with the cellular supply chain.

Challenge

SOTIO had delivered early trials by using its in-house cryo-store and shipping under dry-ice to recipient centres. The plan was to scale this system into the PhIII trial. However, this proved to be impractical and too expensive for three primary reasons:

1. **Inbound supply chain** - challenge of managing the delivery of pre-conditioned packaging to the donor leukapheresis site and coordinating this with patient/clinician availability across multiple countries. There are also limitations in transport including available flights to donor destinations, crossing borders, and different languages
2. **Outbound supply chain** - complexity of managing multiple sites, packaging (construction and disposal), differing regulations, different languages, and return of empty cryo packaging back to storage
3. **Storage and distribution** – product shelf life provided by dry-ice and SOTIO's ability to store the volumes required, limited logistical scope of the study. With future commercialization in mind, it also was impossible to see how this system could be scaled to the volumes anticipated at market launch

Solution

The Fisher BioServices CryoHub^{SM} was the chosen solution for this challenge. Through utilizing the CryoHub infrastructure SOTIO has fully completed enrollment of the VIABLE study and treated more than 1000 patients.

CryoHubs are a network of dedicated advanced therapy storage and distribution facilities strategically located around the globe to support cell and gene therapy supply chains. The facilities provide -20°C, -80°C and -190°C cGMP management capabilities, combined with quality controlled systems for donation kit production & distribution, secondary packaging & labelling, QP release, and monitored and managed cold chain logistics.

Located within the world's key advanced therapy clusters (Europe, North America and Asia), CryoHubs allow therapy developers to utilize standard systems on a global scale and distribute advanced therapies quickly to patients. As part of the wider global operations the CryoHubs can be deployed into over 30 divisional cGMP facilities as market demand grows, ensuring that advanced therapy developers have a scalable solution for commercialization.