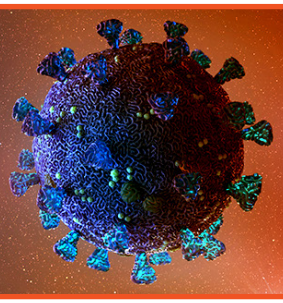
ROOSTERBIO HELPS CELL & GENE THERAPY COMPANY ACCELERATE PROPRIETARY MSC THERAPY FOR COVID IN LESS THAN 6 MONTHS



Company B is a biotechnology company developing cell and gene therapies. With a proprietary cell engineering platform that is currently in Phase I/II trials to treat various indications, the team is looking to leverage their technology to target acute respiratory distress syndrome (ARDS) in COVID patients.

OVERVIEW

A cell and gene therapeutics company with a proprietary cell engineering platform was seeking to quickly develop a mesenchymal stromal cell (MSC)-based therapy to treat COVID patients.

CHALLENGE

To meet the urgency for a rapid COVID response, Company B needs to find a partner who can provide them with a translation ready MSC platform to develop their new MSC therapy as quickly as possible.

SOLUTION

RoosterBio's off-the-shelf hMSC manufacturing ecosystem accelerated their product development by providing RUO hMSC products for early stage, economic evaluation of the system before the program matured into the GMP hMSC product portfolio.

RESULTS

By leveraging RoosterBio's industrialized supply chain of hMSCs and standardized systems, Company B successfully kicked off their MSC program and received their Phase I trial approval from the US FDA in an unprecedented time of less than 6 months.

TRANSLATION READY MSC PLATFORM

As a clinical-stage biopharmaceutical company developing cell and gene therapies, Company B was eager to develop an effective treatment targeting COVID-induced ARDS. Knowing that mesenchymal stromal cells (MSCs) may have potential benefits in modulating cytokine storm in ARDS, the team wanted to leverage their platform to develop a potent MSC therapy quickly. In order to respond to the urgency of this need, Company B needs to find a partner who could provide a translation ready MSC platform to accelerate this new clinical program.

FAST-TRACK MSC PRODUCT DEVELOPMENT

Knowing that RoosterBio's cell and media products have a streamlined path to clinical development, Company B immediately started with RoosterBio's xeno-free development grade hMSCs and expansion media to develop their new product. The robustness and performance reliability of RoosterBio's MSC platform made it easy for Company B scientists to "plug-and-play" this system into their new program. And within a short 3-month period, the team successfully evaluated a promising MSC therapeutic by combining their proprietary cell engineering platform with RoosterBio's MSC ecosystem.

UNPRECEDENTED TIMELINES

With RoosterBio's cGMP product portfolio supported by Type II Master Files, Company B was able to apply for their Phase I clinical trial targeting COVID-induced ARDS in less than 6 months. By leveraging the protocols and high-quality products that RoosterBio provides, Company B scientists developed a robust manufacturing process that was directly implemented in their GMP manufacturing suites. The final stage included a reference to the RoosterBio Type II Master Files which comprise a significant portion of the IND CMC section and shorten the IND application preparation process. In less than 6 months since the launch of their program, Company B's new MSC therapy trial received Phase I approval from the US FDA for COVID-induced ARDS.

WHY IT MATTERS

There has never been a greater urgency and need for companies to leverage the industrialized supply chain of hMSCs that RoosterBio provides. The COVID pandemic presented the perfect need for emerging cell therapy companies to leverage commercially available resources to shorten product development timelines, provide economically palatable solutions and meet clinical milestones in never before seen timeframes.