

Commercial Scale-up of Stem Cells for Regenerative Medicine







MTEC Award: \$6.7M

Sponsor: U.S. Army Medical Research and Development Command

PROBLEM:

Stem cell therapy holds great promise for treating both military and civilians who are severely injured by using cells from a donor to treat another person's injury. Despite this seemingly simplistic approach, the number of stem cell therapies used in current medical practice is underwhelming and impeded by a lack of standardization and robust manufacturing processes.

SOLUTION:

Through MTEC, the U.S. Army Medical Research and Development Command implemented a multi-year program funded BioBridge Global and RoosterBio® to tackle the challenge of developing reproducible and consistent stem cell manufacturing processes that could stand the test of approval by the U.S. Food and Drug Administration.

OUTCOME:

The two commercialized products, RoosterReplenish™-MSC-XF and RoosterVial™-hBM, have supported more than a dozen clinical trials ranging from Phase I to Phase III for a variety of indications.

For example, RoosterVial™-hBM combined with patientisolated macrophages had beneficial effects on recovered COVID-19 patients suffering from interstitial lung disease.

IMPACT:

The two commercialized products help overcome some of the challenges associated with stem cell manufacturing scale-up, with the goal to enable a more rapid clinical translation of stem cell therapies.

RoosterReplenish™-MSC-XF

Animal-free, concentrated feed formulation that is designed to achieve high cell growth while reducing both media preparation time and contamination risk

RoosterReplenish™-MSC-XF - RoosterBio



RoosterVial™-hBM

Animal-free, human bone marrow-derived mesenchymal stem/stromal cells designed for efficient and reproducible expansion and evaluation in clinical studies.

RoosterVial™-hBM - RoosterBio



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