



30 MILLION

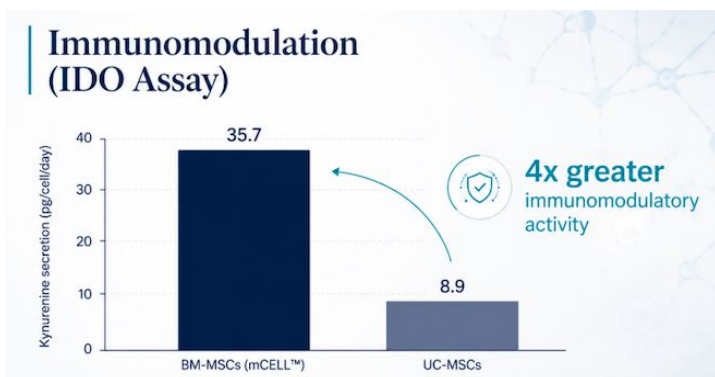
VIABLE BONE MARROW DERIVED MESENCHYMAL STEM CELLS (BM-MSCs)

- ✓ Designed to alleviate pain, increase joint function and speed wound healing.
- ✓ Sourced from screened, healthy donors ages 18–25; no painful aspiration process
- ✓ Fully characterized for biological activity
- ✓ Animal-origin-free and DMSO-free manufacturing platform, designed to preserve cell quality and efficacy



BM-MSCs, like mCELL™, respond to the local tissue environment through coordinated signaling pathways that support **vascularization, matrix repair, and immunomodulation**. Together, these signals limit ongoing tissue damage, support healing, and promote regeneration.

Bone-marrow MSCs, like mCELL™, have the most established clinical evidence and the only lineage with an FDA-approved therapeutic precedent

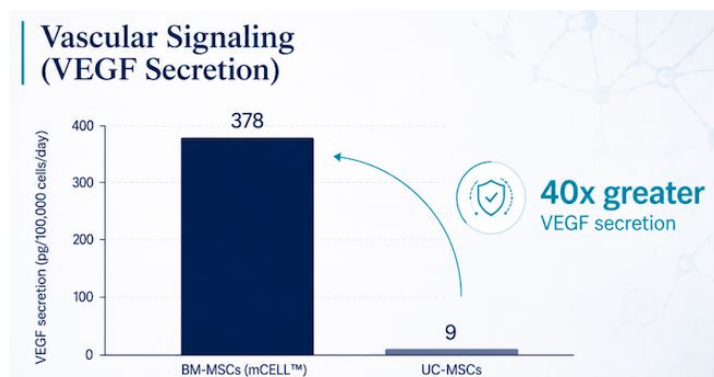


Outperforms Umbilical MSCs

Greater IDO activity and VEGF secretion in standardized laboratory testing

FDA-approved precedent

Only MSC source represented in an FDA-approved therapy



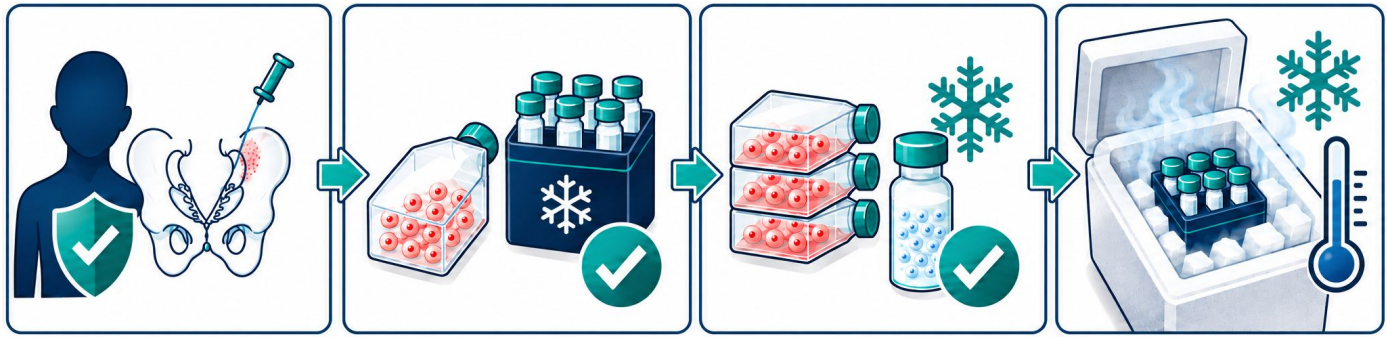
Deepest orthopedic evidence base

Phase 3 knee OA data (146 pts) and randomized DDD data (100 pts; 36 mo)

Rationale grounded in anatomy

Physiologic stem-cell source already leveraged by BMAC and microfracture

From donor-bone marrow to your clinic



Bone Marrow Harvest

Screened, healthy donors age 18-25.
21 CFR 1271 compliant
Accredited Institution.

Master Cell Bank

Qualified and selected for potency.

mCELL™ GMP Manufacturing

Fill, finish & release.
DMSO-free cryopreservation.

mCELL™ Delivery

Shipping in qualified -80°C container. Thaw and inject. Lot-specific COA.



QUALITY STANDARDS & THIRD-PARTY QUALIFICATION



Manufactured in an **FDA-registered, cGMP-compliant facility** with 34+ years of operation



ISO 5 / ISO 7 cleanrooms, environmentally controlled and monitored 24/7



Validated aseptic process, qualified equipment, trained and accountable personnel



End-to-end **lot traceability** from donor to physician

Quality Assurance oversight & Release

Donor eligibility and infectious-disease screening per **21 CFR Part 1271**

Testing is performed by independent laboratories at both ends of the process.

Master Cell Bank: Independently qualified for sterility, mycoplasma, adventitious agents, identity, and karyotype/genetic stability.

Final Product: Every lot tested against predefined release specifications and documented on the Certificate of Analysis.

Safety & identity: sterility, endotoxin, mycoplasma, adventitious agents, MSC surface markers

Viability & function: post-thaw viability, immunomodulatory activity, IDO.