Cellular
INSTITUTE

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MUSE Cells

A patient guide to the science, quality, clinical evidence, and the questions that matter

This guide supports an informed conversation with a qualified physician. It is not medical advice, a guarantee of benefit, or a substitute for standard treatment.



01 · THE BASICS

What are MUSE cells?

Multilineage-differentiating Stress-Enduring cells: rare, naturally occurring cells first described in mesenchymal tissues.

They are identified most commonly by the surface marker **SSEA-3**.

Where they've been reported

Bone marrow, peripheral blood, adipose tissue, skin and connective tissue from multiple organs.

What the lab shows

Stress tolerance, self-renewal, and markers associated with all three embryonic germ layers.

Where that evidence comes from

Laboratory and animal research — not yet broad clinical proof.

01 · THE BASICS

How they differ from standard MSC

01

A rare subpopulation

Standard MSC cultures are heterogeneous. MUSE cells are a rare SSEA-3-positive subpopulation within or derived from them.

02

Identity needs proof

It can't be inferred from "premium MSC," cell dose or a marketing name. It requires product-specific characterization.

03

Results don't transfer

Published research describes defined preparations. Results from one product don't automatically apply to another called "MUSE."

IMPORTANT

MUSE cells are not immune cells.

They are investigated as reparative, pluripotent-like, non-tumorigenic somatic cells. Proposed actions may include:

- Homing to injured tissue
- Cell replacement
- Paracrine & immune signaling



02 · SOURCES

Where MUSE cells come from

Potential source	What it means
Bone marrow	Historically important in published MUSE research, and the source of the investigational CL2020 product used in Japanese studies.
Adipose tissue	MUSE-like SSEA-3-positive cells have been isolated from fat-derived mesenchymal populations in research settings.
Skin / dermal tissue	Where MUSE cells were originally characterized, in human fibroblast and mesenchymal populations.
Peripheral blood	Small numbers circulate and may rise after tissue injury — distinct from a manufactured therapeutic dose.
Other connective tissues	Reported across organs, amniotic membrane and umbilical tissue. Each source requires its own validation.

02 · SOURCES

Autologous or allogeneic?

Autologous

Cells come from the same patient. Manufacturing time, starting material, patient health and process consistency can affect the final product.

Allogeneic

Cells come from a screened donor and may support standardized, ready-to-use manufacturing. Donor eligibility, immune strategy and batch controls remain essential.

You should be told: the exact tissue source, donor relationship, culture history, final MUSE-cell percentage, total viable dose and release-test results — not merely the product's commercial name.

03 · MANUFACTURING

How a clinical-grade product is made

01 Donor & source

Eligibility review, medical history, infectious-disease screening, documented procurement and chain of identity.

02 Cell recovery

Isolation of a mesenchymal cell population from the selected tissue using a defined, validated process.

03 MUSE enrichment

Selection or enrichment by a validated MUSE-defining method, commonly SSEA-3 detection or sorting.

04 Culture & expansion

Controlled media, reagents, vessels, passage limits, environmental monitoring and in-process testing.

05 Harvest & formulation

Washing, concentration, final container, cryopreservation if used, and transport controls.

06 Quality release

Identity, viable count, purity, sterility, mycoplasma, endotoxin and potency reviewed before release.

WHY IT MATTERS

“Same cell type” is not enough.

Two laboratories can start with similar tissue yet produce different mixtures, viability, phenotype, functional activity and risk. Process controls and final-product testing are part of the product.



04 · QUALITY

Reading the Certificate of Analysis

Quality question	What patients should expect
Identity	MUSE-defining phenotype (commonly SSEA-3+), with test method and acceptance criterion
Dose & viability	Total nucleated and viable cells, viability method, intended dose, timing vs. thaw
Purity / composition	Percentage of MUSE-characterized cells, plus relevant non-target cells or residuals
Potency	A validated functional assay linked to the proposed biological activity
Microbial safety	Sterility, mycoplasma and endotoxin results, or a defined rapid-release strategy
Process traceability	Lot number, donor/source code, manufacturing date, culture history, chain of custody
Review & authorization	Qualified release approval linking the COA to the vial administered

Red flag: a brochure, trademark certificate, laboratory license or generic sterility statement is not a substitute for your lot-specific COA.

05 · MECHANISMS

How MUSE cells are proposed to work

Injury sensing & homing

Research proposes they respond to damage signals, including S1P, and migrate toward injured tissue.

Survival under stress

"Stress-enduring" behavior is linked to surviving cellular stress that eliminates many other cells.

Integration & differentiation

Preclinical studies report engraftment and tissue markers; how often and how durably in humans is still under study.

Paracrine & immune effects

Signaling molecules may influence inflammation, cell survival, repair and the local tissue environment.

Low reported tumorigenicity

Described as pluripotent-like yet non-tumorigenic. Controls and long-term follow-up are still required.

A proposed mechanism explains how a treatment *might* work. Clinical benefit must still be shown in well-designed human trials.

06 · HUMAN EVIDENCE (MOSTLY CL2020)

What has been studied in people

Condition	What the study contributes	What it cannot establish
Subacute ischemic stroke	Randomized, placebo-controlled trial, 35 participants (25 CL2020, 10 placebo); functional-improvement signal.	Proof for all stroke patients, doses, routes or other products.
Acute myocardial infarction	First-in-human study, 3 patients, IV CL2020 after reperfusion; feasibility observations.	Efficacy: no control group, very small sample.
Cervical spinal cord injury	10 participants, one IV CL2020 dose; safety and feasibility reported.	Comparative benefit or use in all injuries.
ALS	Single-center, open-label Phase 2, repeated IV CL2020; safety and exploratory effects.	Disease modification (small, uncontrolled).
Other indications	Epidermolysis bullosa, neonatal hypoxic-ischemic encephalopathy and other serious conditions.	Use for unrelated conditions or "longevity."

BOTTOM LINE

Promising, but preliminary.

Published CL2020 outcomes apply to CL2020 as studied. A different manufacturer must independently demonstrate identity, comparability, safety and clinical relevance.



07 · CLAIMS

Brand, license and the actual product

MUSE is a scientific category

A rare stress-enduring, pluripotent-like somatic cell population, commonly characterized with SSEA-3 and reported in multiple tissues and labs.

Licenses cover defined IP

They may cover patents, isolation methods, protocols, know-how or trademarks — not a universal biological definition or a performance guarantee.

Evidence must match the product

CL2020 findings can't be assumed for every SSEA-3+ product, and a different platform shouldn't borrow claims without comparability evidence.

Cellular Institute position: trust is earned through transparent sourcing, validated manufacturing, lot-specific SSEA-3 characterization, viable dose, safety and potency testing, traceability and honest discussion of uncertainty — not through a name alone.

08 · SAFETY

Potential risks and uncertainties

⚠

Infusion reactions: fever, chills, headache, allergic or inflammatory responses.

⚠

Infection or endotoxin exposure if collection, culture, handling or administration controls fail.

⚠

Clotting, vascular or cardiopulmonary complications, depending on product, dose, route and risk factors.

⚠

Immune or donor-related risks with allogeneic material; long-term risks may be incompletely known.

⚠

No benefit, temporary benefit, unexpected worsening, or delay of proven care.

⚠

Risks from other medications, central lines, sedation, local injections or other protocol components.

08 · SAFETY

A responsible patient pathway

01

Medical evaluation

Diagnosis, timeline, severity, active treatments, goals and realistic endpoints.

02

Eligibility

Infection, cancer history, immune status, clotting risk, organ function, pregnancy.

03

Product review

Source, manufacturer, regulatory status, COA, dose, route, chain of custody.

04

Informed consent

Investigational status, alternatives, uncertainties, costs and included follow-up.

05

Follow-up

Predefined measures, adverse-event reporting, records shared with your specialist.

Seek immediate care after treatment for: difficulty breathing, chest pain, fainting, severe headache, new weakness, confusion, high fever, facial swelling, persistent vomiting or rapidly worsening symptoms.

09 · YOUR CONSULTATION

Questions to bring to your physician

01 What is the exact cell product and tissue source?

02 Is it autologous or allogeneic? How was the donor screened?

03 How is MUSE identity shown? What percentage is SSEA-3 positive?

04 What total viable dose will I receive, and how is viability measured?

05 May I review the lot-specific COA before treatment?

06 What sterility, mycoplasma, endotoxin and potency tests were done?

07 What published evidence applies to this exact product, dose, route and condition?

08 Is it investigational for my condition? What are the standard alternatives?

09 What adverse events are known, and what emergency support is available?

10 How will outcomes and complications be measured and reported?

09 · SOURCES

Selected references

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Medical & regulatory note

Availability and legal status vary by country and indication. "Investigational," "registered," "licensed facility," "patented" and "approved therapy" are not interchangeable. Treatment abroad is not thereby FDA-approved. This guide makes no promise of cure or outcome.

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