Montana
EXPERIMENTAL TREATMENT REVIEW BOARD

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montanaetrb.org

RDL-2026-003

Dezawa MuseCells® (DMC)

DEFERRED PENDING ADDITIONAL INFORMATION

Review Decision Letter · Decided October 26, 2026

Legal basis: SB 535 (69th Leg., Ch. 621) · ARM 37.106.3301-3325

APPLICANT	MuseCell Innovations Pte. Ltd. (Singapore, SG).
TREATMENT	Dezawa MuseCells® (DMC): allogeneic, SSEA-3-enriched Muse-cell product derived from perinatal (umbilical cord) tissue, manufactured in the United States by BioBridge Global. Single intravenous infusion of 20 × 10^6 viable cells for the neurologic cohorts (pediatric ceiling 2 × 10^6 cells/kg), or a single intra- articular or periarticular injection of up to 5, 10 or 20 × 10^6 cells by joint size for the musculoskeletal cohort. Administration at an ETC only, with 12 months of safety follow-up (Protocol DMC-MT- 001, v1.2).
INDICATION	(1) Adults with acquired neurologic injury or disease with persistent functional impairment; (2) children aged 2 to 17 with acquired static encephalopathy with motor impairment, including cerebral palsy; (3) adults with musculoskeletal degenerative or inflammatory conditions.
SUBMISSION	Final submission: October 12, 2026 (dossier v1.2 and scientific letter of Prof. Mari Dezawa); supplementary adverse-event materials: October 17, 2026.
REVIEW MEETING	October 26, 2026, 1-2:30pm Mountain Time. Quorum confirmed; conflict-of-interest declarations (none) confirmed on the record; Applicant session and Q&A minuted; deliberation and vote in closed session.
DECISION	**Deferred pending additional information. Vote: 4 for, 0 against, 1 absent.**
EFFECTIVE-NESS	No approval is in effect. This is not a disapproval. The Board will reconsider the application on a resubmission that addresses Section 2.

1. Treatment summary

DMC is an allogeneic cell therapy enriched for cells expressing the surface marker SSEA-3. The release specification requires at least 70% SSEA-3-positive cells; the Applicant states that the remainder of each lot consists of CD105-positive mesenchymal stromal cells from the same donor.

The Applicant relies on the Japanese clinical program for CL2020, a bone-marrow-derived Muse-cell product, including the stroke study CL2020-CI-1 (25 treated; single intravenous dose of 15 × 10^6 cells; 52-week follow-up) and studies in spinal cord injury, ALS, epidermolysis bullosa, myocardial infarction and neonatal hypoxic-ischemic encephalopathy. It seeks qualification under the qualified medical institution pathway (50-12-102(1)(b), MCA). DMC differs from CL2020 in tissue source and manufacturing process. The Montana protocol also adds indications and patient populations, raises the reference intravenous dose from 15 to 20 × 10^6 cells, and introduces intra-articular and periarticular administration, which the cited CL2020 studies did not use.

The Applicant's scientific expert states that CL2020 is no longer manufactured and that "no direct bridging or testing has been done to compare the two" (Dezawa letter, October 12, 2026, §6.1). It is asking a recognized regulatory authority to accept the Japanese data so that development can begin at Phase 2.

2. Requirements for reconsideration

Requirement 1 - Statutory qualification (threshold)
A resubmission must establish one of the following:

a. Regulatory authority determination. Applicant is currently engaged in discussions with a recognized regulatory authority regarding CL2020 and DMC comparability. Written correspondence from that authority accepting that the CL2020 clinical data support clinical investigation of the DMC product proposed for Montana without a new Phase 1 study. If the authority instead requires a Phase 1 study or a safety lead-in for DMC, the Board will consider the data from that study once available. The Board will align with the authority's determination on this question.

b. Phase 1 trial of DMC. A completed Phase 1 clinical trial of the DMC product, or a trial equivalent to Phase 1, conducted under a recognized regulatory authority, with prospective, protocol-defined safety assessment. Consistent with the Board's Guidance on Phase 1 Clinical Trial Requirements (September 29, 2026), "routine clinical use, case reports, retrospective chart review, or passive adverse-event reporting do not by themselves constitute a Phase 1 clinical trial."

Requirement 2 - Product characterization
The resubmission shall provide any feedback from a recognized regulatory authority on the DMC chemistry, manufacturing and controls (CMC) package, and shall address: (a) the composition and biology of the non-SSEA-3 fraction of the product; (b) tissue factor expression and the associated thrombotic risk of the perinatal product; and (c) ectopic tissue formation and tumorigenicity for the perinatal product specifically.

Requirement 3 - Product-specific safety data
Adverse-event data shall be provided for DMC itself, separately from CL2020, as tables of adverse events by grade and relationship and of serious adverse events. Statements of human use (including units sold or patients treated) shall state their source, period and the method of adverse-event collection.

Requirement 4 - Scope of cohorts
The Board recommends that a resubmission be limited to adults with acquired neurologic injury or disease. If the pediatric or musculoskeletal cohorts are retained, the resubmission must include additional human safety data supporting them. No human data were presented for local (intra-articular or periarticular) administration.

Requirement 5 - Informed consent
The informed consent materials shall be revised for all cohorts to describe best-case, worst-case and most likely outcomes without promising benefit. If the pediatric cohort is retained, the materials shall apply a higher standard of information for parents and providers than patient assent and parental judgment alone.

3. Required determinations (ARM 37.106.3316(6))

Determination	Finding	Board position	Basis (summary)
Statutory qualification (50-12-102(1), MCA)	Not met on the current record	Unanimous	The Phase 1 predicate is CL2020, the board does not have sufficient reason to consider the CL2020 studies as equivalent to Phase 1 data for DMC at this time. However, confirmation of comparability by a recognized regulatory authority would be acceptable.
Safety standards equivalent to or higher than recognized regulatory authorities (16(6)(a)(i))	Not reached	Unanimous	Depends on Requirement 1. For the adult neurologic cohort, the Board sees a clear path once Requirement 1 is met. Pediatric data are limited; there are no human data for musculoskeletal local administration.
Informed consent comprehensive and understandable (16(6)(a)(ii))	Not met	Unanimous	Consent materials are too thin for all populations and inadequate for the pediatric cohort. See Requirement 5.
Risk-benefit demonstrates a reasonable safety profile (16(6)(a)(iii))	Not met on the current record	Unanimous	Requires human safety data with the DMC product, not general claims of use without adverse events. If a recognized regulatory authority permits DMC to enter Phase 2 without a safety lead-in, the Board expects that to support a favorable analysis for serious adult neurologic indications with limited options, subject to its own analysis per indication.
Alternative treatments appropriately evaluated (16(6)(a)(iv))	Not reached	-	Not separately deliberated. To be assessed on resubmission.
Risk level and outside-ETC administration (16(6)(f))	Risk level: High. Not suitable for administration outside an ETC.	Unanimous	Allogeneic viable-cell product administered intravenously or locally; outside-ETC administration was not proposed.

Statutory qualification recital: on the record submitted, the Board could not find reasonable grounds for treating the requirements of 50-12-102(1), MCA as satisfied. The Board makes no finding that DMC is unsafe.

4. Principal matters deliberated

(1) Product identity: DMC has not been shown to be the same product as CL2020 for purposes of the Phase 1 requirement, given the differences in tissue source and manufacturing process and the absence of bridging data.

(2) Human use data: the Board cannot treat retrospective data, reports of commercial use, or adverse-event reporting as a Phase 1 under its statutory obligations.

(3) Reliance on a recognized regulatory authority: the Board will align with that authority's determination on whether the CL2020 clinical data support clinical investigation of DMC without a new Phase 1 study.

(4) Cohorts: the Board recommends that a resubmission begin with adult neurologic patients.

(5) Deferral rather than disapproval: the Board deferred so that it can act on the authority's response and on new data that meets the statutory bar. Per-member vote rationales are preserved in the Review Record.

5. Resubmission

The Applicant may resubmit at any time. A resubmission should state how it addresses each Requirement in Section 2 and follow the Board's standard packet format: an executive summary, consistent file naming, and adverse-event tables organized by grade, relationship and seriousness. The Board will reconsider at its next scheduled meeting after a complete resubmission and may engage an independent chemistry, manufacturing and controls expert for that review. Records of this review are preserved for at least five years (16(6)(d)).

6. Disclaimers and reliance

This deferral reflects the Board's professional judgment on the record submitted. It is not a finding that DMC is unsafe or ineffective, is not a determination of the product's status under federal or any other law, and is not medical advice (Submission Agreement 8.2-8.4). Responsibility for development, manufacture, regulatory compliance and supply rests with the Applicant and its manufacturers and distributors.

MONTANA EXPERIMENTAL TREATMENT REVIEW BOARD ETRB

Matt Kaeberlein

Matt Kaeberlein, PhD - Chair, for the Board.

Signed on November 2, 2026. Docusign Envelope ID: 040FF825-ED1A-8ABC-8056-4917C5CD5EC3