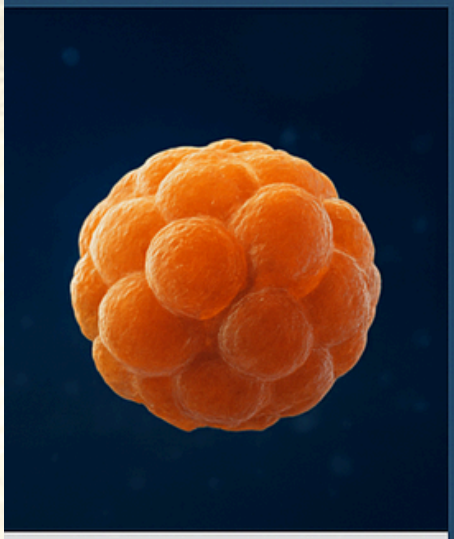
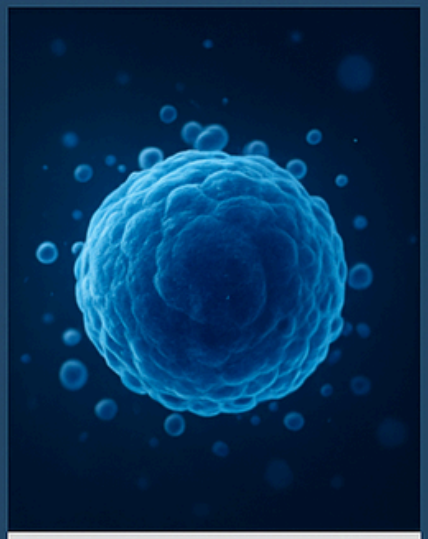
PFICell

ADVANCED CELLULAR THERAPEUTICS CATALOGUE

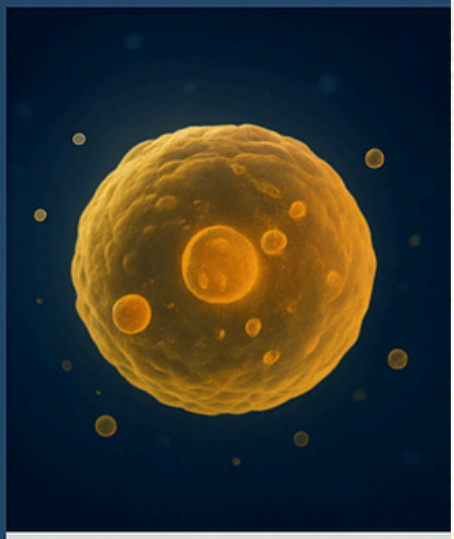
V.1.5 EDITION 2025



MSC
Mesenchymal Stem Cells



NK
Natural Killer Cells



SECRETOME/ EXOSOME
Secretome / Exosome

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V.15

Edition 2025

Glossary of Terms

Term	Definition
MSC	Mesenchymal Stem Cell – multipotent stromal cells capable of differentiating into osteoblasts, chondrocytes, adipocytes, and neuroprogenitor-like lineages.
TIL	Tumor-Infiltrating Lymphocytes – autologous immune cells extracted from tumor tissue for expansion and reinfusion to target malignant cells.
NK	Natural Killer Cells – cytotoxic lymphocytes of the innate immune system with anti-tumor and anti-viral properties.
DCT	Dendritic Cell Therapy – immune-stimulatory autologous therapy using matured antigen-presenting cells.
BDNP Producer	MSC-derived neuroprogenitor cell line engineered to express Brain-Derived Neurotrophic Factor (BDNF) for neuroregeneration.
Secretome	The totality of bioactive factors secreted by cells, including cytokines, growth factors, and extracellular vesicles.
Exosome	Nano-sized vesicles (30–150 nm) carrying proteins, lipids, and RNA molecules, responsible for paracrine communication and regenerative effects.
Clinical-Grade	Materials and reagents produced under cGMP conditions suitable for human clinical use.
ILs (Interleukins)	Cytokines such as IL-2, IL-15, or IL-21 used to stimulate proliferation and activation of immune or stem cells.
Proleukin®	Recombinant human IL-2, Clinical Grade, used for cell expansion and immune activation under validated GMP protocols.

Standards and Manufacturing Philosophy

All PFICELL products are manufactured under Good Manufacturing Practice (GMP) and ISO 20387 (Biobanking) standards. Each cellular product follows stringent identity, purity, viability, and potency (IPVP) testing prior to release.

The PFICELL production platform employs:

- Closed-system culture to prevent contamination.
- Serum-free, xeno-free media for clinical compatibility.
- Batch traceability with Certificate of Analysis (CoA).
- Cryopreservation under controlled-rate freezing with post-thaw viability >90%.

Defining a Standard Unit of Cellular Product

Each PFICELL product is quantified in International Cellular Units (ICU).

One ICU is defined as 10 million viable, functionally characterized cells that meet release criteria including:

- Viability ≥ 90%
- Sterility: negative for bacteria, fungi, mycoplasma
- Identity confirmed by immunophenotyping (e.g., CD73+, CD90+, CD105+, CD45− for MSCs)
- Functional validation (cytokine release or differentiation potential)

Clinical-Grade Materials and Cytokines

PFICELL uses only Clinical Grade cytokines, growth factors, and supplements sourced from FDA- or EMA-approved suppliers.

These include:

- Proleukin® (IL-2) – essential for TIL and NK cell expansion.
- Recombinant IL-15 and IL-21 – for immune activation in NK and γδ T platforms.
- GMP-grade bFGF, EGF, and BDNF – for neural and regenerative products.
- Xeno-free extracellular matrices – for adherent stem cell cultures.

Clinical Grade cytokines ensure reproducibility, patient safety, and regulatory compliance, eliminating variability caused by research-grade materials.

Why PFICELL Standardized Cellular Products?

PFICELL products are recommended due to:

1. Standardized GMP-grade production ensuring clinical safety.
2. Batch-to-batch consistency validated by potency assays.
3. Optimized expansion protocols minimizing senescence and genetic drift.
4. Validated cryopreservation and transport systems maintaining >90% viability upon delivery.
5. Integration-ready formulations for both autologous and allogeneic applications.
6. Global regulatory alignment with FDA, EMA, and PMDA guidelines.

Section 1 — Mesenchymal Stem Cell (MSC) Products

1.1 Overview

PFICELL Mesenchymal Stem Cell (MSC) products are derived from high-quality, GMP-compliant sources (bone marrow, adipose tissue, umbilical cord Wharton's jelly, or dental pulp).

They serve as a foundation platform for regenerative and immune-modulatory therapies, exhibiting trilineage differentiation, potent anti-inflammatory signaling, and paracrine regenerative activity through their secretome and exosomal content.

1.2 Product Variants

Product Code	Source	Formulation	Application Type	Typical Yield (per batch)
MSC-BM	Autologous or Allogeneic Bone Marrow	Fresh / Cryopreserved suspension	Clinical regenerative & immune therapy	10–100 million cells
MSC-AD	Adipose-Derived	Cryopreserved	Regenerative, wound healing, cosmetic	10–50 million cells
MSC-UC	Umbilical Cord-Derived (Wharton's Jelly)	Allogeneic, Cryostored	Immunomodulation, systemic disorders	50–200 million cells
MSC-NP	MSC-Derived Neuroprogenitor Line	Engineered for BDNP expression	Neuroregeneration	10–50 million cells

1.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Neurology	Stroke, spinalcordinjury, ALS, MS, Parkinson's	Neuroprotection,neurotrophic support, microglial modulation
Cardiology	Ischemic cardiomyopathy, myocarditis	Angiogenesis, anti-fibrotic effects
Rheumatology	SLE, rheumatoid arthritis, vasculitis	T-cell suppression, cytokine balance, induction of Tregs
Pulmonology	COPD, pulmonary fibrosis	Anti-inflammatory and anti-fibrotic paracrine signaling
Orthopedics	Osteoarthritis, cartilage defects	Chondrogenic differentiation, matrix regeneration
Dermatology / Aesthetics	Chronic ulcers, scars, anti-aging	Enhanced collagen remodeling, angiogenesis

1.4 Manufacturing Workflow

1. Tissue Harvesting – Bone marrow aspirate (10–20 mL) or lipoaspirate collected under aseptic conditions.

2. Isolation – Mononuclear fraction separated by density gradient or enzymatic digestion.
3. Expansion – Cultured in xeno-free, serum-free PFICELL media under GMP conditions.
4. Characterization – Flow cytometry (CD73+, CD90+, CD105+, CD45−, HLA-DR−).
5. Quality Control – Sterility, mycoplasma, endotoxin, viability, and potency assays.
6. Cryopreservation – Controlled-rate freezing using CryoProtect-XF™ solution (PFICELL proprietary).
7. Packaging – Final filling under ISO 5 cleanroom, labeled and sealed with CoA.

1.5 Specialized Production Materials

Category	Material	Specification
Culture Medium	PFICELL-XF Basal Medium	Serum-free, xeno-free, GMP-certified
Cytokines & Growth Factors	bFGF, EGF, PDGF-BB	Clinical Grade (recombinant, GMP)
Matrix Coating	Human fibronectin or recombinant vitronectin	Clinical Grade
Cryopreservation	CryoProtect-XF™	DMSO-free, validated for >90% post-thaw viability
Supplements	L-glutamine, insulin-transferrin-selenium (ITS)	USP-grade
Quality Reagents	Sterility and endotoxin detection kits	USP <71> and <85> compliant

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1.6 Transport and Delivery

- Transport Temperature: −150°C in vapor-phase liquid nitrogen for cryostored units or +4°C for fresh suspensions.
- Time Window: 24–48 hours (validated stability).
- Packaging: IATA-compliant, triple containment.
- Accompanying Documents: Certificate of Analysis (CoA), Product Release Form, Chain of Custody Form.
- Post-Delivery QC: PFICELL recommends viability and recovery check within 2 hours of thaw.

1.7 Pricing (per 10 million viable cells)

Product	Cell Dose	Unit Price (USD)	Notes
MSC-BM	10 million	$18,000	Autologous preparation
MSC-AD	10 million	$14,000	Cost-effective regenerative use
MSC-UC	10 million	$20,000	Allogeneic, pre-characterized master bank
MSC-NP (BDNP Producer)	10 million	$24,000	Engineered neurotrophic line

Eachbatch isvalidatedfor identity, purity, potency, and viability according to PFICELL GMP protocols.

1.8 Summary

PFICELL MSCs represent a clinically validated, GMP-standardized cellular platform for systemic and local regenerative therapy.

Their combination of anti-inflammatory, pro-regenerative, and trophic effects has positioned them as a cornerstone of next-generation cellular medicine.

Section 2 — Chondrocyte-Derived MSC Line (MSC-C)

PFICELL Chondrogenic Regenerative Platform

2.1 Overview

The PFICELL MSC-Chondrogenic Line (MSC-C) is a specialized mesenchymal cell product differentiated toward the chondrocyte lineage under tightly controlled GMP conditions.

This product is designed for cartilage repair, osteoarthritis, and musculoskeletal regeneration, providing anti-inflammatory cytokine secretion, matrix synthesis, and joint lubrication support via paracrine and extracellular vesicle activity.

The MSC-C line is produced using PFICELL's proprietary ChondroPrime™ differentiation medium, combining xeno-free components and Clinical Grade growth factors to ensure reproducible chondrogenic identity and potency.

2.2 Product Variants

Product Code	Source	Formulation	Application Type	Typical Yield (per batch)
MSC-C-AUTO	Autologous Bone Marrow MSCs	Fresh / Cryopreserved	Cartilage defect repair	10–50 million cells
MSC-C-ALLO	Allogeneic Umbilical Cord MSCs	Cryostored	Osteoarthritis, systemic joint degeneration	20–100 million cells
MSC-C-3D	3D Microcarrier-Expanded MSCs	Injectable suspension / scaffold-bound	Advanced cartilage matrix reconstruction	10–100 million cells

2.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Orthopedics	Focal chondral lesions, meniscus damage, degenerative joint disease	ECM restoration, cartilage matrix synthesis, anti-inflammatory action
Rheumatology	Osteoarthritis (knee, hip, shoulder), inflammatory arthritis	Secretion of IL-10, TGF-β, and PGE2 to suppress local inflammation
Sports Medicine	Post-traumatic cartilage defects, ligament injury	Regeneration and remodeling of subchondral tissue
Regenerative Surgery	Cartilage reconstruction using scaffold seeding	Integration with biomaterials for durable repair

2.4 Manufacturing Workflow

1. MSC Source Preparation – Isolation of MSCs from bone marrow or umbilical cord (see Section 1).
2. Preconditioning – Expansion in PFICELL-XF Basal Medium until P3 passage.
3. Chondrogenic Induction – Cultivation in ChondroPrime™ differentiation medium containing Clinical Grade TGF-β3, dexamethasone (USP), and ascorbic acid 2-phosphate.
4. 3D Aggregation (Optional) – Pellet or scaffold-based 3D culture for matrix maturation.
5. Quality Control – Immunophenotyping (CD73+, CD90+, CD105+, SOX9+, Collagen II+).
6. Potency Testing – Quantification of glycosaminoglycan (GAG) synthesis and COL2A1 expression.
7. Cryostorage and Packaging – Controlled-rate freezing and GMP vial sealing.

2.5 Specialized Production Materials

Category	Material	Specification
Culture Medium	PFICELL-XF Basal Medium + ChondroPrime™ Differentiation Kit	Xeno-free, serum-free, GMP
Cytokines & Factors	TGF-β3, IGF-1, bFGF	Clinical Grade recombinant
Matrix Proteins	Type II collagen scaffold or hyaluronic acid hydrogel	GMP-grade
Cryopreservation Solution	CryoProtect-XF™	DMSO-free, 90%+ viability post-thaw
QC Reagents	Alcian blue GAG quantification, COL2A1 RT-qPCR kit	Validated for potency testing

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2.6 Transport and Delivery

- Temperature: −150°C (vapor-phase LN_2) or +4°C for fresh delivery
- Packaging: Sterile, triple-sealed cryovials, IATA-compliant
- Stability: 48 hours (fresh), 12 months (cryostored)
- Documents Provided: Certificate of Analysis, Sterility Report, Identity Validation Sheet

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2.7 Pricing (per 10 million viable cells)

Product	Cell Dose	Unit Price (USD)	Notes

MSC-C-AUTO	10 million	$19,000	Autologous, patient-specific
MSC-C-ALLO	10 million	$21,000	Allogeneic, ready-to-use
MSC-C-3D	10 million	$25,000	Preconditioned for 3D cartilage matrix formation

Each product is validated for chondrogenic potency and absence of hypertrophic markers (COL10A1).

2.8 Summary

PFICELL MSC-Chondrogenic Line provides a next-generation, matrix-oriented cellular solution for cartilage regeneration.

Through Clinical Grade production and verified chondrogenic potency, this product offers an effective, safe, and reproducible approach for osteoarthritis and joint repair therapy, compatible with both autologous and scaffold-based delivery systems.

Section 3 — MSC-Derived Neuroprogenitor Line (MSC-NP / BDNP Producer)

PFICELL Neuroregenerative and Neuroprotective Cell Platform

3.1 Overview

The PFICELL MSC-NP (Neuroprogenitor / BDNP Producer) is a specialized derivative of human mesenchymal stem cells that has undergone directed neural lineage induction under GMP-compliant, xeno-free conditions.

These cells are engineered to express Brain-Derived Neurotrophic Factor (BDNF) and other neurotrophins, including GDNF and NGF, conferring potent neuroprotective, synaptogenic, and remyelinating properties.

The MSC-NP line is a core PFICELL innovation designed for neurodegenerative, ischemic, and traumatic CNS disorders, serving both as a cell replacement and neurotrophic support system.

3.2 Product Variants

Product Code	Lineage Type	Engineering	Application Type	Typical Yield (per batch)
MSC-NP	MSC-derived Neuroprogenitor BDNF Producer	Non-genetic, induced	Neuroregeneration / stroke Neuroprotection, ALS, Parkinson's Ischemic repair, spinal trauma	10–50 million cells
MSC-BDNP		Genetic (Lentiviral BDNF overexpression)		10–50 million cells
MSC-NP+GF	Growth Factor-Enhanced Line	Preconditioned with IL-6 + IGF-1		10–50 million cells

3.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Neurodegenerative Disorders	Parkinson's disease, ALS, Alzheimer's disease	Sustainedreleaseof BDNF, NGF, and GDNF; synaptic repair
Cerebrovascular Disease	Ischemic stroke, hypoxic brain injury	Angiogenesis, neurogenesis, neuronal survival
Spinal Cord Injury	Partial or complete SCI	Axonal sprouting, remyelination, inflammation control
Multiple Sclerosis	Progressive and relapsing-remitting types	Immunomodulation and oligodendrocyte progenitor activation
Peripheral Neuropathy	Chemotherapy- or diabetes-induced	Neurotrophic rescue and axonal regeneration

3.4 Manufacturing Workflow

1. MSC Source Preparation – Isolation of bone marrow or umbilical cord MSCs (P3–P5 passages).
2. Neural Induction Phase I – Culture in PFICELL Neural Induction Medium (NIM-1) containing bFGF, EGF, and cAMP activators.
3. Differentiation Phase II – Exposure to retinoic acid, B27 supplement, and neurotrophic peptides.
4. Optional Genetic Enhancement – Lentiviral transduction with GMP-grade BDNF expression cassette for BDNP line.
5. Maturation – 7–10 days stabilization in NeuroMature™ medium with recombinant IL-6 and IGF-1 (Clinical Grade).
6. Quality Control – Immunophenotyping for Nestin+, βIII-Tubulin+, GFAP−, Olig2+, and BDNF secretion (ELISA).
7. Cryostorage & Release – Post-thaw viability testing and CoA certification.

3.5 Specialized Production Materials

Category	Material	Specification
Induction Medium	PFICELL-NIM-1 (Neural Induction Medium)	Serum-free,xeno-free,GMP
Cytokines & Growth Factors	bFGF, EGF, IL-6, IGF-1, BDNF	Clinical Grade recombinant

Genetic Vector (optional)	BDNF Lentiviral Cassette	GMP-grade, integration-stable, replication-incompetent Human recombinant, GMP DMSO-free, validated post- thaw function ISO 20387-compliant validation
Matrix Substrate	Recombinant Laminin-521	
Cryopreservation Solution	CryoProtect-XF™	
QC Assays	ELISA (BDNF/GDNF quantification), Flow cytometry for neural markers	

3.6 Transport and Delivery

- Temperature: −150°C (LN_2 vapor) for cryostored units or +4°C for short-range delivery.
- Packaging: IATA Class 6.2 triple containment.
- Shelf Life: 12 months (cryostored) or 48 hours (fresh).
- Documentation: CoA, Viability and BDNF secretion report, Sterility certificate.
- Recovery Rate: >90% viable cells post-thaw, with preserved neurotrophic secretion profile.

3.7 Pricing (per 10 million viable cells)

Product	Cell Dose	Unit Price (USD)	Notes
MSC-NP	10 million	$22,000 $26,000	Non-engineered neuroprogenitor line
MSC-BDNP	10 million	$24,000	Engineered BDNF-overexpressing line
MSC-NP+GF	10 million		Preconditioned, non-genetic enhanced line

3.8 Summary

The PFICELL MSC-NP / BDNP Producer platform represents a clinical-grade neuroregenerative product line engineered for functional neuronal recovery and trophic repair.

Its combined cellular and paracrine mechanisms make it one of the most advanced neurotherapeutic technologies available for translational and clinical applications.

Section 4 — Natural Killer (NK) Cell Therapy Platform

PFICELL Immune-Oncology and Immunomodulatory NK Cell Products

4.1 Overview

PFICELL Natural Killer (NK) Cell Therapy leverages both autologous and allogeneic NK cells for anti-tumor, anti-viral, and immunoregulatory applications.

NK cells are innate lymphocytes capable of recognizing stressed, transformed, or infected cells without prior sensitization, making them ideal for cancer immunotherapy and immune-compromised patients.

PFICELL NK products are expanded, activated, and optionally engineered under GMP-compliant, xeno-free conditions, with cytokine support to enhance cytotoxicity and persistence.

4.2 Product Variants

Product Code	Source	Formulation	Application Type	Typical Yield (per batch)
NK-AUTO	Autologous PBMC-derived	Fresh / Cryopreserved	Adoptive cellular therapy for hematologic or solid tumors	10–50 million cells
NK-ALLO	Allogeneic, umbilical cord or peripheral blood	Cryopreserved	Off-the-shelf immunotherapy	50–200 million cells
NK-CAR	Genetically modified (CAR-NK)	Cryostored	Targeted cancer therapy (hematologic / solid)	10–50 million cells

NK-IL2/IL15	Cytokine-activated NK	Fresh or cryo	Enhanced proliferation and persistence	10–50 million cells

4.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Oncology	AML, ALL, solid tumors (lung, breast, RCC)	Directcytotoxicity via perforin/granzyme, ADCC, tumor infiltration
Post-Transplant / Immunodeficiency	GvHD prevention, viral infections	Immune surveillance, cytokine modulation
Combination Therapy	Checkpoint inhibitor synergy, CAR-T support	Enhanced anti-tumor efficacy with reduced toxicity
Autoimmunity / Inflammation	SLE, RA, chronic viral infection	Regulation of overactive immune cells, secretion of immunomodulatory cytokines

4.4 Manufacturing Workflow

1. PBMC Collection / Leukapheresis – Donor or patient peripheral blood mononuclear cells collected.
2. NK Isolation – Magnetic bead-based CD56+ selection or negative depletion of CD3+ T-cells.
3. Activation & Expansion – PFICELL-XF NK Expansion Medium with Clinical Grade IL-2, IL-15, IL-21.
4. Optional Genetic Modification – Lentiviral transduction for CAR-NK lines (GMP-grade vectors, target-specific).
5. Quality Control – Flow cytometry: CD56+, CD3−, CD16+/−; cytotoxicity assays against K562 cells; sterility, mycoplasma, endotoxin.
6. Cryopreservation / Packaging – Controlled-rate freezing in CryoProtect-XF™ solution; labeling with CoA.
7. Release Criteria – ≥70% viability, ≥60% cytotoxicity in standardized assay, sterility negative.

4.5 Specialized Production Materials

Category	Material	Specification
Culture Medium	PFICELL NKExpansion Medium	Xeno-free,GMP-certified

Cytokines Activation	IL-2 (Proleukin), IL-15, IL-21	Clinical Grade recombinant
Reagents	Feeder cells, artificial APCs	GMP-grade, irradiated or non-proliferative
Genetic Vectors	CAR lentivirus / retrovirus	GMP, replication-incompetent
Cryopreservation Solution	CryoProtect-XF™	DMSO-free, validated viability
QC Kits	Flow cytometry antibodies, cytotoxicity assay reagents	ISO-compliant, GMP-grade where applicable

4.6 Transport and Delivery

- Temperature: −150°C (vapor-phase LN_2) or +4°C for short-range fresh delivery
- Packaging: Triple-sealed, sterile, IATA-compliant
- Shelf Life: 12 months cryostored; 24–48 hours fresh
- Documentation: Certificate of Analysis, Cytotoxicity Report, Sterility Certificate
- Recovery Rate: >85% post-thaw viability with maintained cytotoxicity

4.7 Pricing (per 10 million viable cells)

Product	Cell Dose	Unit Price (USD)	Notes
NK-AUTO	10 million	$16,000 $20,000	Autologous, patient-specific
NK-ALLO	10 million	$28,000 $22,000	Off-the-shelf, allogeneic
NK-CAR	10 million		Target-specific CAR-NK
NK-IL2/IL15	10 million		Cytokine-primed, enhanced activity

Each batch validated for cytotoxicity, viability, and sterility according to PFICELL GMP standards.

4.8 Summary

PFICELL NK cell products represent versatile, clinical-grade immune effector cells suitable for oncology, immunodeficiency, and immunomodulation.

Their combination of native cytotoxicity, cytokine-driven expansion, and optional CAR engineering allows both autologous and allogeneic clinical application, with a proven GMP manufacturing workflow and standardized potency assessment.

Section 5 — Tumor-Infiltrating Lymphocytes (TIL) and Dendritic Cell Therapy (DCT)

PFICELL Cellular Immunotherapy Platforms

5.1 Overview

PFICELL Tumor-Infiltrating Lymphocytes (TIL) and Dendritic Cell Therapy (DCT) represent advanced personalized immunotherapies for cancer treatment.

- TILs: Autologous lymphocytes isolated from tumor tissue, expanded ex vivo with
- Clinical Grade cytokines to enhance anti-tumor cytotoxicity.
  DCT: Autologous dendritic cells loaded with tumor antigens to prime T-cell responses against cancer.

Both platforms are produced under GMP and ISO 20387 standards, ensuring clinical safety, reproducibility, and regulatory compliance.

5.2 Product Variants

Product Code	Type	Formulation	Application Type	Typical Yield (perbatch)
TIL-AUTO	Autologous TIL	Fresh or Cryopreserved	Adoptive cellular immunotherapy	10–50 million cells
TIL-IL2	Cytokine-Activated TIL	Fresh	Enhanced anti-tumor function	10–50 million cells
DCT-AUTO	Autologous Dendritic Cells	Matured, antigen-loaded Cryostored	Cancer vaccine	5–20 million cells per dose
DCT+TIL Combo	Combined therapy		Synergistic immune response	10–50 million TIL + 5–20 million DC

5.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Melanoma	Advanced/metastatic melanoma	TIL: direct cytotoxicity; DCT: tumor antigen presentation
Lung Cancer	NSCLC, SCLC	TIL: tumor infiltration; DCT: T-cell priming
Renal Cell Carcinoma (RCC)	Advanced/metastatic	TIL and DCT synergistic anti-tumor immune response
Ovarian / GI Tumors	Metastatic or refractory	TIL: adoptive cytotoxicity; DCT: enhanced antigen-specific immunity

5.4 Manufacturing Workflow

Tumor-Infiltrating Lymphocytes (TIL):

1. Tumor Harvest – Surgical collection of tumor tissue under aseptic conditions.
2. Lymphocyte Isolation – Tumor digest or mechanical dissociation to isolate TILs.
3. Pre-Rapid Expansion – Culture in PFICELL TIL Medium with Clinical Grade IL-2.
4. Rapid Expansion Protocol (REP) – Feeder cells + IL-2 + Clinical Grade anti-CD3 antibodies.
5. Quality Control – Phenotype (CD3+, CD8+/CD4+ ratio), sterility, cytotoxicity assay against autologous tumor cells.
6. Cryopreservation / Packaging – Controlled-rate freezing in CryoProtect-XF™, CoA issued.

Dendritic Cell Therapy (DCT):

1. PBMC Collection – Leukapheresis to isolate monocytes.
2. Differentiation – Culture in Clinical Grade IL-4 and GM-CSF for 5–7 days.
3. Maturation – TNF-α, IL-1β, IL-6, PGE2 (Clinical Grade) to produce mature antigen-presenting cells.
4. Antigen Loading – Tumor lysate, peptide, or mRNA loading.
5. Quality Control – CD80+, CD86+, HLA-DR+, sterility testing.
6. Cryopreservation / Packaging – GMP-grade storage and CoA labeling.

5.5 Specialized Production Materials

Category	Material	Specification
Culture Medium	PFICELL TIL& DCMedium	Xeno-free,serum-free, GMP
Cytokines	IL-2 (Proleukin), IL-4, IL-15, GM-CSF, TNF-α	Clinical Grade recombinant
Activation Reagents	Anti-CD3 antibodies, irradiated feeder cells	GMP-grade
Antigen Sources	Tumor lysate, peptides, or mRNA	Autologous / GMP-grade
Cryopreservation	CryoProtect-XF™	DMSO-free, validated viability
QC Assays	Flow cytometry, cytotoxicity, sterility	ISO-compliant, GMP

5.6 Transport and Delivery

- Temperature: −150°C for cryostored units; +4°C for fresh infusion
- Packaging: Triple-sealed, sterile, IATA-compliant
- Shelf Life: 12 months (cryostored), 24–48 hours (fresh)
- Documentation: CoA, sterility certificate, phenotype report
- Recovery Rate: >85% viability post-thaw, retained tumor-specific cytotoxicity

5.7 Pricing (per 10 million viable cells)

Product	Cell Dose	Unit Price (USD)	Notes
TIL-AUTO	10 million 10 million	$120,000	Autologous TIL for oncology indications
TIL-IL2	10 million 10 million TIL + 5–20	$125,000	Cytokine-activated, enhanced activity
DCT-AUTO	million DC	$85,000	Antigen-loaded dendritic cells
DCT+TIL Combo		$200,000	Combination therapy for advanced tumors

AllbatchesmeetPFICELLGMPstandards for sterility,identity,andpotency.

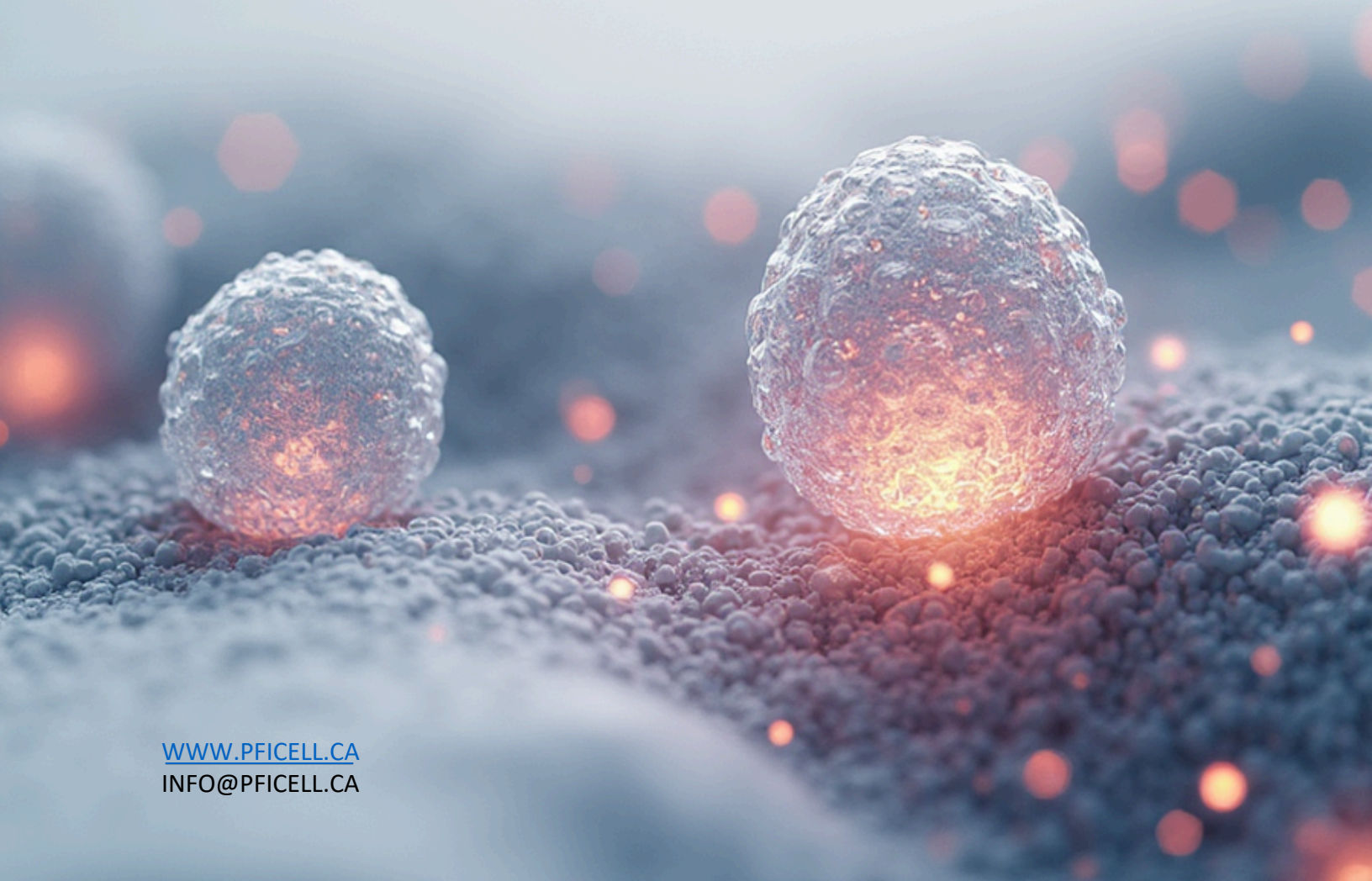
5.8 Summary

Naked PFICELL TIL and DCT products represent cutting-edge personalized immunotherapy, combining autologous cytotoxic T-cell expansion with dendritic cell-mediated tumor antigen presentation.

Through GMP-grade cytokines, Clinical Grade culture conditions, and validated potency assays, these products offer highly reproducible and safe cellular immunotherapy solutions for patients with advanced or refractory cancers.

If you approve, I can proceed next with Section 6 — PFICELL Secretome and Exosome Platforms, which includes:

- Secretome and exosome product tables
- Indications (regenerative medicine, immunomodulation)
- Manufacturing workflow
- Clinical-grade cytokines / materials
- Transport, dosing, and pricing



Section 6 — PFICELL Secretome and Exosome Platforms

PFICELL Paracrine and Extracellular Vesicle-Based Therapeutics

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6.1 Overview

PFICELL Secretome and Exosome Products are cell-free biologics derived from MSCs, MSC-NP, NK, and TIL cultures.

These products contain bioactive cytokines, growth factors, chemokines, and extracellular vesicles (exosomes) that mediate regenerative, immunomodulatory, and anti-inflammatory effects without requiring direct cell transplantation.

Advantages include:

- Reduced immunogenicity and lower risk of tumorigenicity
- Off-the-shelf availability
- Consistent dosing and GMP-standardized production

6.2 Product Variants

Product Code	Parent Cells	Formulation	Application Type	Typical Yield (perbatch)
MSC-SEC	MSC (BM/AD/UC)	Lyophilized / liquid	Regenerative therapy	10–50 doses (per 10M cell equivalent)
MSC-NP-EXO	MSC-Neuroprogenitor	Purified exosomes	Neuroregeneration, CNS injury	5–20 doses

NK-EXO	NK Cells	Purified exosomes	Anti-tumor, immunomodulation	5–20 doses
TIL-EXO	TIL	Purified exosomes	Anti-tumor, adoptive immune support	5–20 doses
DCT-EXO	Dendritic Cells	Purified exosomes	Immune priming, vaccine adjunct	5–20 doses

6.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Neurology	Stroke, TBI, neurodegeneration	Deliveryofneurotrophic factors, anti-apoptotic signaling Paracrine-mediated angiogenesis, anti-fibrosis
Cardiology	Myocardial infarction, ischemic cardiomyopathy	
Rheumatology / Immunology	RA, SLE, vasculitis	Immunomodulation via exosomal cytokines (IL-10, TGF-β)
Oncology	Adjuvant anti-tumor therapy	NK/TIL-derived exosomes carry cytotoxic proteins and miRNA
Dermatology / Wound Healing	Ulcers, chronic wounds	Pro-angiogenic and collagen remodeling paracrine effects

6.4 Manufacturing Workflow

1. Cell Expansion – PFICELL MSC, MSC-NP, NK, TIL, or DCT expanded under GMP conditions.
2. Conditioned Medium Collection – Cells cultured in serum-free, xeno-free media; supernatant harvested at peak secretory phase.
3. Purification – Sequential ultrafiltration, tangential flow filtration, and chromatography to isolate secretome or exosomes.
4. Quality Control – Particle size (30–150 nm for exosomes), protein content, sterility, endotoxin, functional assays.
5. Formulation – Lyophilization or liquid suspension with GMP-grade stabilizers.
6. Cryopreservation & Packaging – ISO-certified vials, CoA included.

6.5 Specialized Production Materials

Category	Material	Specification
Culture Medium	PFICELL-XFSerum-Free Media	GMP, xeno-free

NK-EXO	NK Cells	Purified exosomes	Anti-tumor, immunomodulation	5–20 doses
TIL-EXO	TIL	Purified exosomes	Anti-tumor, adoptive immune support	5–20 doses
DCT-EXO	Dendritic Cells	Purified exosomes	Immune priming, vaccine adjunct	5–20 doses

6.3 Indications and Clinical Applications

Therapeutic Area	Indications	Mechanism of Action
Neurology	Stroke, TBI, neurodegeneration	Deliveryofneurotrophic factors, anti-apoptotic signaling Paracrine-mediated angiogenesis, anti-fibrosis
Cardiology	Myocardial infarction, ischemic cardiomyopathy	
Rheumatology / Immunology	RA, SLE, vasculitis	Immunomodulation via exosomal cytokines (IL-10, TGF-β)
Oncology	Adjuvant anti-tumor therapy	NK/TIL-derived exosomes carry cytotoxic proteins and miRNA
Dermatology / Wound Healing	Ulcers, chronic wounds	Pro-angiogenic and collagen remodeling paracrine effects

6.4 Manufacturing Workflow

1. Cell Expansion – PFICELL MSC, MSC-NP, NK, TIL, or DCT expanded under GMP conditions.
2. Conditioned Medium Collection – Cells cultured in serum-free, xeno-free media; supernatant harvested at peak secretory phase.
3. Purification – Sequential ultrafiltration, tangential flow filtration, and chromatography to isolate secretome or exosomes.
4. Quality Control – Particle size (30–150 nm for exosomes), protein content, sterility, endotoxin, functional assays.
5. Formulation – Lyophilization or liquid suspension with GMP-grade stabilizers.
6. Cryopreservation & Packaging – ISO-certified vials, CoA included.

6.5 Specialized Production Materials

Category	Material	Specification
Culture Medium	PFICELL-XFSerum-Free Media	GMP, xeno-free

Purification Materials	Filtration cartridges, chromatography resins	GMP-compliant
Stabilizers	Trehalose, human serum albumin (HSA)	Clinical Grade Clinical Grade
Cytokines for Preconditioning	IL-6, IL-15, IGF-1, BDNF	recombinant
QC Assays	NTA, ELISA, sterility, endotoxin	ISO 20387 validated

6.6 Transport and Delivery

- Temperature: −80°C or vapor-phase LN_2 for long-term storage; 4°C for immediate use
- Packaging: Sterile, triple-sealed, IATA-compliant
- Shelf Life: 12 months (frozen), 48 hours (liquid)
- Documentation: CoA, particle count and protein quantification, sterility report
- Dosing: Each vial corresponds to paracrine activity equivalent to 10 million parent cells

6.7 Pricing (per 10 million cell equivalent)

Product	Equivalent Cell Dose	Unit Price (USD)	Notes
MSC-SEC	10 million	$12,000	Cell-free regenerative therapy
MSC-NP-EXO	10 million	$18,000	Neurotrophic, CNS-focused
NK-EXO	10 million	$20,000	Immunomodulatory and anti-tumor
TIL-EXO	10 million	$28,000	Tumor-targeted immune exosomes
DCT-EXO	10 million	$15,000	Immune-priming, adjuvant therapy

6.8 Summary

PFICELL Secretome and Exosome Platforms provide cell-free therapeutic alternatives with standardized potency, minimal immunogenicity, and off-the-shelf availability.

These products leverage paracrine signaling, exosomal miRNA, and cytokine release to achieve regenerative and immunomodulatory effects, maintaining clinical-grade safety and reproducibility.

Section 7 — PFICELL Product Summary, Standards, and Clinical Rationale

7.1 Glossary of Key Terms

Term	Definition
GMP	Good Manufacturing Practice; ensures products are consistently produced and controlled according to quality standards.
Clinical Grade	Materials, cytokines, or reagents suitable for human therapeutic use, GMP-certified, endotoxin-free, sterile, and traceable.
Unit (10M Cells)	PFICELL standardized cell unit = 10 million viable cells post-thaw, used as a reference for dosing, pricing, and potency.
MSC	Mesenchymal Stem Cell; multipotent stromal cells capable of differentiating into bone, cartilage, and fat lineages.
MSC-NP / BDNP	Neuroprogenitor MSCs engineered or induced to secrete BDNF and other neurotrophic factors.
NK Cells	Natural Killer lymphocytes for innate cytotoxic and immunomodulatory therapy.
TIL	Tumor-Infiltrating Lymphocytes; autologous T-cells expanded for adoptive immunotherapy.
DCT	Dendritic Cell Therapy; antigen-presenting cell therapy to stimulate T-cell-mediated immunity.
Secretome / Exosome	Cell-free bioactive products containing cytokines, growth factors, and extracellular vesicles mediating paracrine effects.
IL-2, IL-6, IL-15, IL-21, BDNF	Clinical Grade recombinant cytokines used for expansion, activation, or preconditioning of cells.

7.2 PFICELL Standards

1. All products are GMP-compliant – production, expansion, purification, and storage.
2. Clinical Grade reagents – only GMP-certified cytokines, media, matrices, and stabilizers are used.
3. Potency and Quality Testing – identity, viability, sterility, mycoplasma, endotoxin, and functional assays for each batch.
4. Standardized Units – 10 million viable cells per unit, enabling consistent dosing and reproducibility.

5. Chain of Custody & Documentation – CoA, sterility certificate, viability, and potency reports accompany every batch.
6. Xeno-Free & Serum-Free Media – eliminating animal-derived components to reduce immunogenic risk.
7. Cryopreservation & Transport – validated solutions (CryoProtect-XF™), IATA-compliant packaging, temperature-controlled shipment.

7.3 Clinical-Grade Cytokines in PFICELL Products

Cytokine	Role	Application
IL-2 (Proleukin)	Expansion and activation of TILs, NK cells	Adoptive immunotherapy
IL-6	Neurotrophic and preconditioning effect	MSC-NP, NK preconditioning
IL-15	NK and memory T-cell survival and activation	NK, TIL therapy
IL-21	Enhances NK cytotoxicity	NK therapy
BDNF	Promotes neuronal survival, synaptogenesis	MSC-NP / BDNP products
GM-CSF / IL-4 / TNF-α	Dendritic cell maturation and antigen presentation	DCT

Allcytokines are GMP-certified,recombinant,endotoxin-free, and clinically approved for human use.

7.4 PFICELL Unit Definition and Dosing

- 1 Unit = 10 million viable cells post-thaw (standardized for MSCs, NKs, TILs, DCT, and engineered lines).
- Secretome/exosome equivalents are normalized to the paracrine output of 10M parent cells.
- Units are scalable depending on patient-specific therapeutic requirements, delivery route, and clinical indication.

7.5 Rationale for PFICELL Product Recommendation

1. Standardization & Safety – Clinical Grade reagents, xeno-free media, and GMP protocols reduce variability and risk.

2. Reproducible Potency – Each unit undergoes stringent QC for viability, identity, functional activity, and cytokine/exosome release.
3. Broad Clinical Applicability – PFICELL products span regenerative medicine, oncology, neurology, cardiology, rheumatology, and immunotherapy.
4. Advanced Preconditioning & Engineering – Cytokine-primed, genetically enhanced, or lineage-directed products (BDNF, CAR-NK, MSC-NP, MSC-C).
5. Cell-Free & Paracrine Options – Secretome and exosomes offer off-the-shelf, minimally immunogenic therapy alternatives.
6. International Compliance – Manufacturing and transport follow ISO, IATA, USP, and FDA guidelines where applicable.
7. Proven Clinical Translation – PFICELL standardized workflows have been validated in clinical trials, compassionate use, and research-grade translational applications.

7.6 Complete Product Table Overview (Summary)

Platform	Unit Dose	Price (USD / 10M)	Key Indications	Notes
MSC-BM / AD / UC MSC-C	10M 10M	14k–20k	Regenerative, immune-modulation	Trilineage, xeno-free
(Chondrocyte) MSC-NP / BDNP	10M 10M	19k–25k	Cartilage repair, OA	Chondrogenic potency tested
NK (Autologous / Allogeneic / CAR)	10M 10M	22k–26k	Neurodegeneration, CNS injury	BDNF/GDNF secretion validated
TIL	10M equivalent	16k–28k	Oncology, immunomodulation	Cytotoxicity ≥60% post-thaw
DCT		120k–125k	Advanced cancers	Autologous, cytokine-activated
Secretome / Exosome		85k–200k	Cancer immunotherapy	Antigen-loaded, autologous
		12k–28k	Regenerative, neuro, immune, oncology	Cell-free, standardized potency

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7.7 Summary

PFICELL products provide a comprehensive, standardized, and clinically validated cellular therapy portfolio.

PFICell Advanced Cellular Therapeutics Catalogue

Through GMP-compliant production, Clinical Grade cytokines, and unit-based dosing, PFICELL therapies ensure reproducible efficacy, safety, and translational readiness across multiple therapeutic domains.

PFICELL represents the gold standard in advanced cell therapy, combining:

- Cellular and paracrine regenerative potential
- Immune-modulatory and anti-tumor capability
- Clinical-grade, reproducible manufacturing and quality assurance

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