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# *Modulating immune response through advanced cell therapeutics*

January 2025

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# Company Overview

**PRIVATE**
**Founded in 2018**, the company has established a strong foundation in the **field of cell-based therapeutics** and developed a robust **patent portfolio**

**MULTI-ASSET**
**3 proprietary platforms**, with the common focus of **modulating the immune system** and treating **inflammatory-driven diseases**

**LATE-STAGE**
Commencing in 2025 a **pivotal Phase 2/3 trial** in Idiopathic Inflammatory Myopathy (IIM); several **completed Phase 1** clinical trials with an outstanding **safety profile** and initial **clinical benefits** across multiple indications

**REGULATORY SUCCESS**
**FDA Fast Track** and **Orphan Drug Designations** granted in Idiopathic Inflammatory Myopathy (IIM), affirming our clinical achievements

# Platforms Overview

## Restem-L

### Autoimmunity

**Off-the-shelf** proprietarily **conditioned** umbilical lining-derived stem cells (*ULSC*s) developed to target **orphaned & refractory auto-immune** diseases

## aNK

### Immunosenescense

Uniquely **activated natural killer** cells designed to reduce **immuno-senescence** and combat **age-associated disorders**

## Restem-X

### Orthopedics

**Secretome-based** product offering ground-breaking therapeutic properties in **orthopedic** treatments

# Experienced Management Team & Advisory Board

## Management Team

Andres Isaias

*Executive Chairman & Chief Executive Officer*

Rafael Gonzalez, PhD

*Chief Development & Science Officer*

Keith March, MD, PhD

*Chief Medical Officer*

Nelson Cabatuan

*Chief Financial Officer*

Barb Eppler-Mossler PhD

*Sr. VP of Clinical & Regulatory*

Brian Pla

*Chief Commercial Officer*

## Scientific Advisory Board

**Robert Sackstein, MD, PhD**

SVP for Global Health Affairs, Florida International University

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**Guenther Koehne, MD, PhD**

Deputy Director and Chief of Blood & Marrow Transplant and Hematologic Oncology

Memorial Sloan Kettering Cancer Center · Baptist Health South Florida

**Robert Negrin, MD, PhD**

Division Chief, Blood and Marrow Transplant Program, Medical Director, Clinical Bone Marrow Transplantation Laboratory

Stanford University



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# Advancing Pipeline of Restem Programs

| Program | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 | Milestone |
|---|---|---|---|---|---|---|
| **Restem-L: Autoimmune Diseases** | Idiopathic Inflammatory Myopathy (IIM)* | | | | | Phase 2/3 to initiate in 1H 2025 |
| | Rheumatoid Arthritis *Refractory* | | | | | Phase 2 IND has been FDA Authorized |
| | Ulcerative Colitis *Refractory* | | | | | Phase 2 submission in 2H 2025 |
| **aNK: Longevity** | Frailty / Aging-Disorders | | | | | Phase 1 submission in 1H 2026 |
| **Restem-X: Secretome** | Osteoarthritis | | | | | Phase 1 submission in 2H 2025 |

* FDA Fast Track and Orphan Drug designations granted



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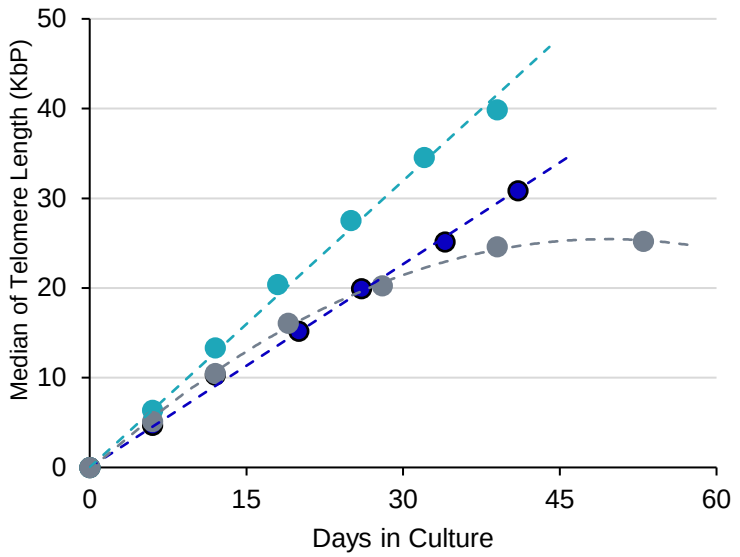
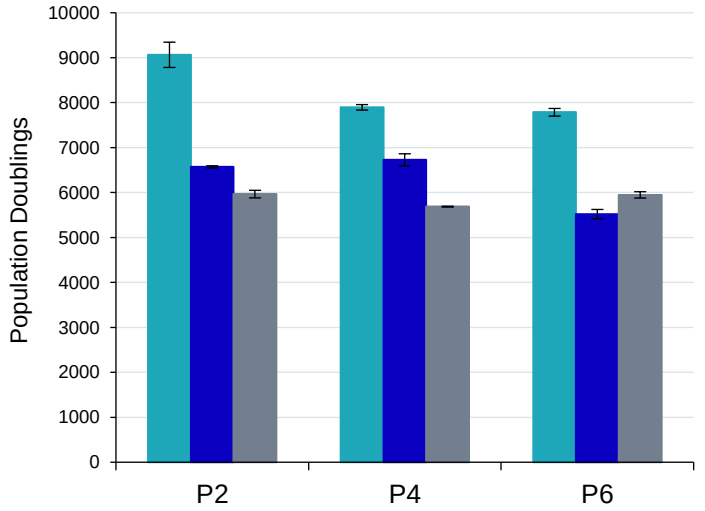
# Restem-L - Younger, Stronger, Best-In-Class Cellular Product

## Superior Growth Capacity



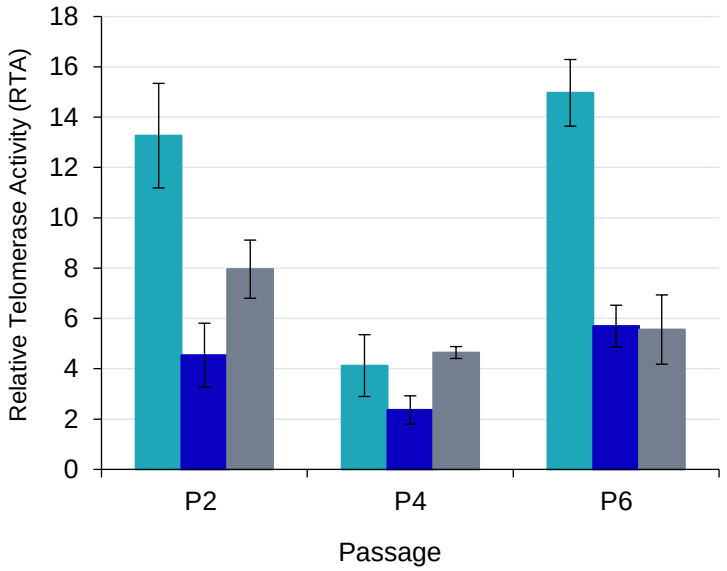

Exceptional proliferative ability ensures a greater yield of high-quality cells for scalable and effective therapies

## Longer Telomeres Across Passages

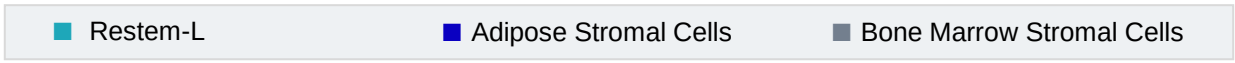



Restem-L maintains youthful robust characteristic throughout multiple passages ensuring long-term therapeutic potential

## Higher Telomerase Activity in Later Passages




Enhanced telomerase activation supports stronger DNA repair mechanism and younger cells




**Superior Properties than Typical Mesenchymal Stem Cells**



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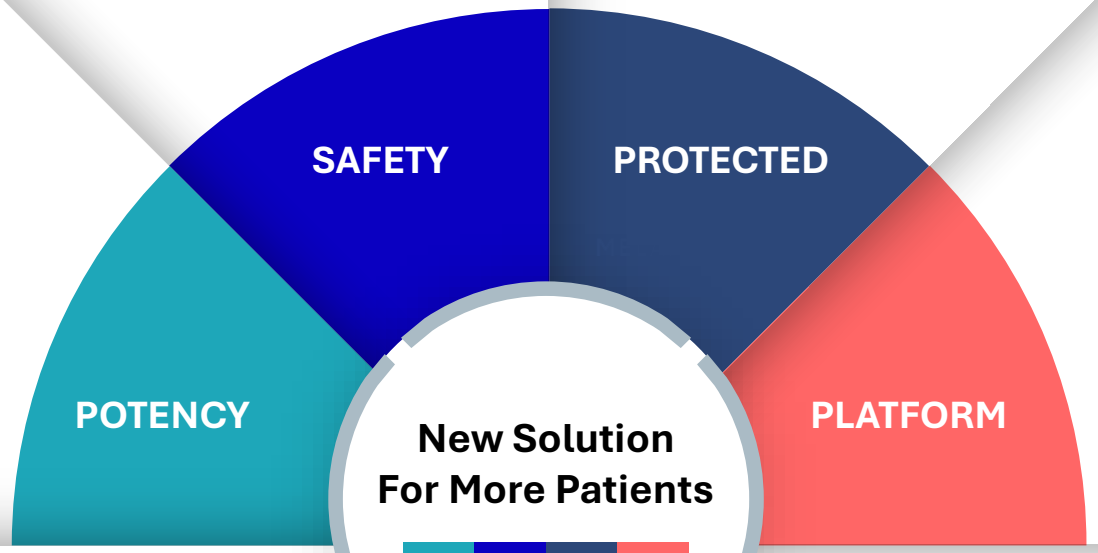
# Restem-L - Key Pillars

- ✓ Highly potent
- ✓ Multi-potent marker expression with regenerative potential
- ✓ Source of growth factors, nucleic acids, cytokines and exosomes

- ✓ Superior safety to other cellular products
- ✓ No systemic toxicity
- ✓ Self-limiting expression
- ✓ Avoids immune system detection

- ✓ Patent-protected through materials & methods
- ✓ Proprietarily conditioned
- ✓ Use patent-protected per indication




- ✓ Allogeneic, off-the-shelf product
- ✓ Cost-effective therapeutic
- ✓ Broad application across multiple indications



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# Restem-L - Overcoming the Quintessential Cell Therapeutics Manufacturing Challenges

| Scalability | Cost | Time | Consistency | Inventory |
|---|---|---|---|---|
| Massively scalable, 3 master and working cell banks with a capability to produce **3 million doses** | Cost of manufacturing is extremely beneficial, with a production cost of **<$2,200 / dose** | Faster manufacturing time, **6-week** timeline from master / working cell bank to final product | Superior **lot-to-lot consistency** and reproducibility, complete uniformity among donors and cell lines | **180 doses** of GMP cells in inventory ready for use in clinic trials, with quick turn-around for more |

**Uniquely positioned to support clinical trials and mass commercialization of cell-based products**

# Addressing the Growing Need for Autoimmune Therapies

## Increasing Prevalence of Autoimmune Diseases

Autoimmune diseases affect approximately 1 in 10 individuals globally and its prevalence is growing [1]

## Unmet Medical Needs

Current treatments focus on symptom management, not disease modification, and carry significant side effects including immunosuppression and organ toxicity. Innovative therapies are urgently needed for refractory patients who are unresponsive to SoC*

## Cost

The autoimmune disease market is estimated at $150 billion / year across multiple autoimmune indications [2]

## Potential for Regenerative Solutions

Restem-L provides a natural alternative to conventional treatments, with the potential to offer long-term benefits, such as immunomodulation and tissue repair, with an excellent safety profile

*SoC; standard of care


1. Miller FW. The increasing prevalence of autoimmunity and autoimmune diseases: an urgent call to action for improved understanding, diagnosis, treatment, and prevention. Curr Opin Immunol. 2023 Feb;80:102266.
2. www.einpresswire.com/article/495486226/autoimmune-disease-therapeutics-market-nears-150-billion-by-2025-market-is-witnessing-a-strong-presence-of-late-stage-pipeline-drugs




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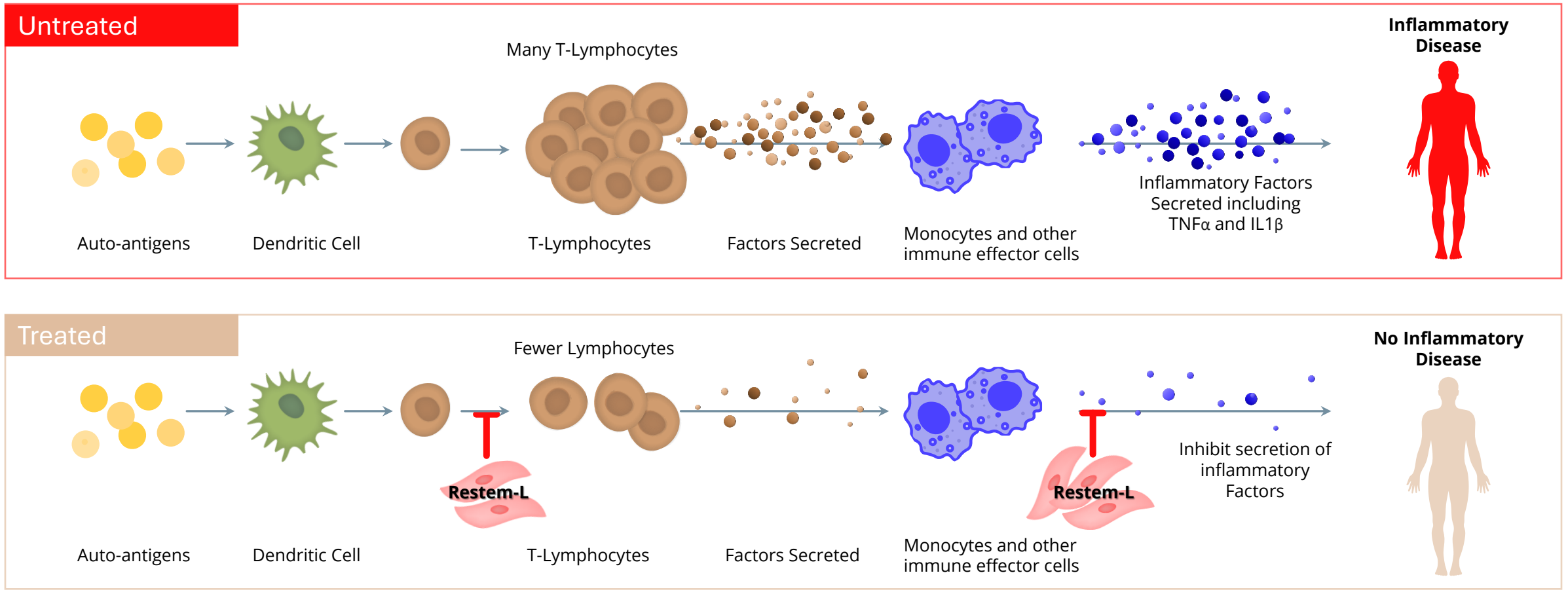
# Restem-L Strongly Modulates the Inflammatory Response

## Inflammation is the driving force of autoimmune tissue injury




**Restem-L Modulates Lymphocyte and Monocyte Factor Secretion to Treat Disease**



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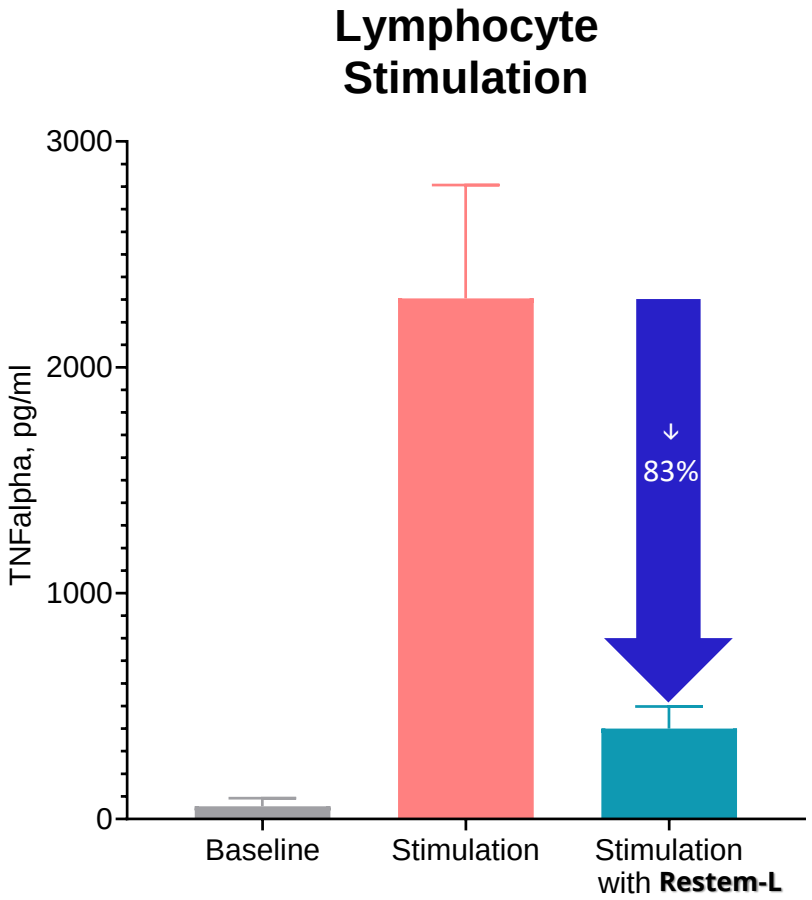
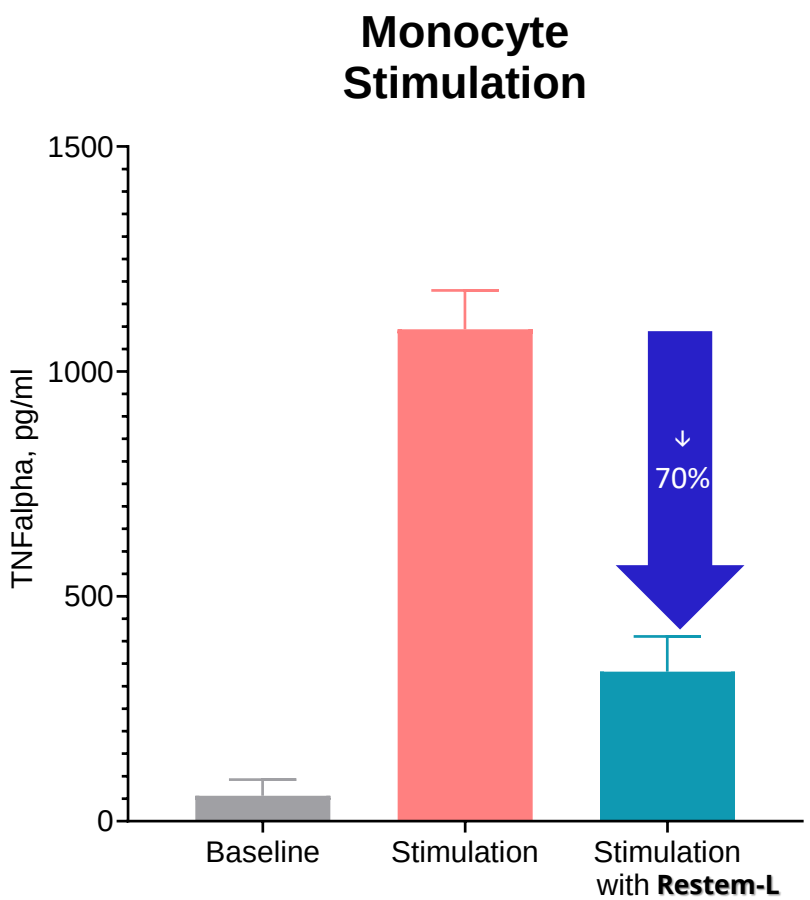
# Restem-L - Strongly Reduced Inflammatory Responses of White Cells in Clinical Trial Patients




**Restem-L markedly suppresses TNFα, a strong mediator of inflammation**



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# Restem-L in Adult Idiopathic Inflammatory Myopathy (IIM)

## Idiopathic Inflammatory Myopathy

IIM is a chronic autoimmune disease, with Polymyositis/Dermatomyositis/ (PM/DM) being the primary IIM subtypes. PM is an autoimmune disease marked by inflammation and weakness of the skeletal muscles and DM is a form of polymyositis that is associated with skin rashes, in addition to muscle inflammation

## Unmet Medical Needs

IIM affects ~58,000 people in the US alone*

Currently, the only treatment for these disorders is immunosuppressive drugs, which can be associated with significant toxicity and other severe side effects

## Cost and Current Treatment

IIM is currently managed with long-term use of steroids like prednisone, which have many serious side effects, or with Intravenous Immunoglobulin (IVIg) which is commonly in short supply and costs $100,000+ yearly

## Restem-L Potential

Phase 1 data presented at ACR 2024 demonstrated that treatment with Restem-L in IIM (both in PM and DM) resulted in symptomatic improvements as well as a 35% reduction in steroid dosage within 6 months.  The data illustrates the ability of Restem-L to modulate the inflammatory response and potentially treat the disease.



* www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2022.842586/full

# IIM Phase 1 Study Design

## Open-label, dose escalation trial to investigate Restem-L therapy in IIM (both in PM and DM)

**Inclusion Criteria**

Adults, age ≥18 years old

Diagnosis of definite or probable PM or DM

Patients with PM will either be positive for a myositis-associated antibody or have undergone evaluation to exclude mimics

**Treatment**


**Endpoints**

Evaluation of Safety with escalating doses

Preliminary Efficacy:

Total Improvement Score (TIS), from baseline;

Changes in steroid dosing during the course of standard clinical care

**Institution / Investigator**: University of Florida Medical Center / Michael Bubb, MD (Principal Investigator)



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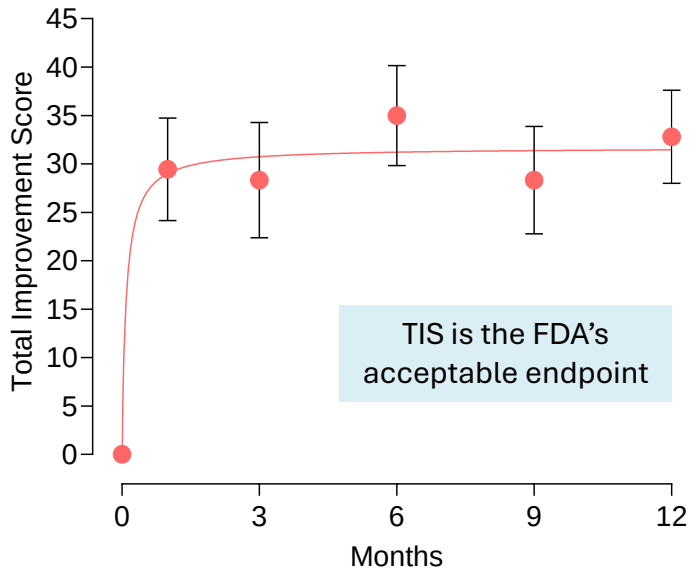
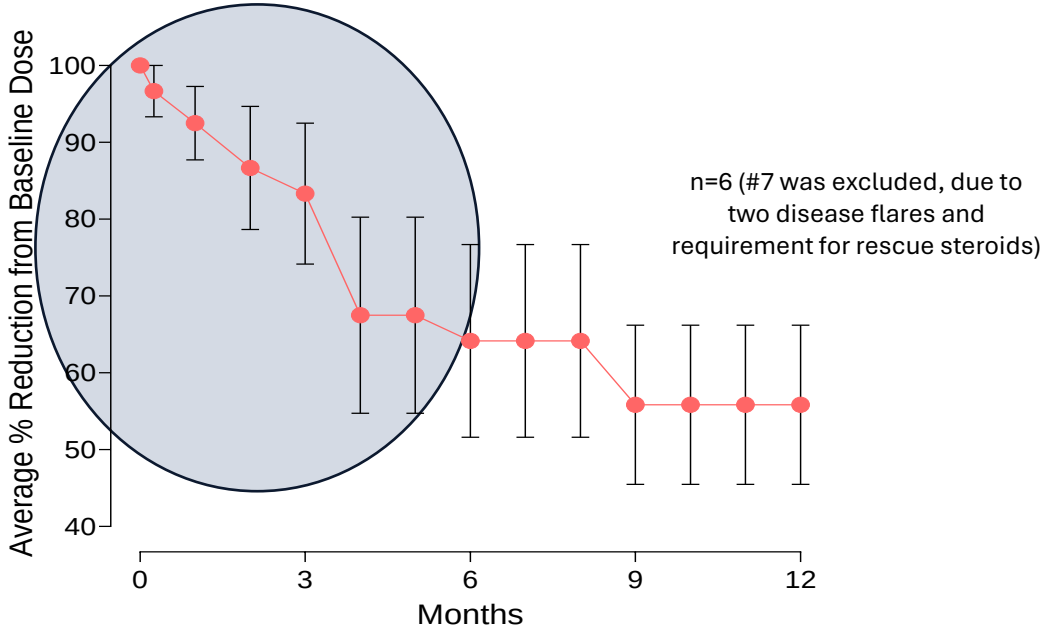
# Restem-L Improved Symptoms while Reducing Steroids Use in IIM

## Durable Improvement




- The Total Improvement Score (TIS) averaged for all participants is within the 20-40% point range; 20% is considered a meaningful improvement by the FDA and Key Opinion Leaders
- The overall improvement in various scales was seen concurrently with a reduction in 6 of the 7 participants of the Prednisone daily dose

## Reduction of Required Prednisone Dose




- The average daily dose of Prednisone could be tapered by more than 5.5 mg (*chronic use of as little as 2.5 mg daily leads to increased adverse side effects)*
- 7 out of the 9 participants used Prednisone daily
- 6 out of the 7 daily users of Prednisone had an average of ~50% decrease in their steroid use



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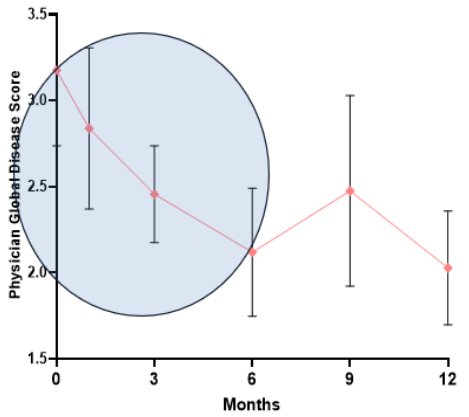
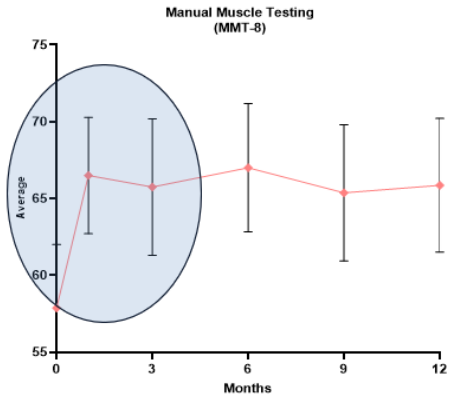
# TIS Score – Shows Improvement on all 6 Sub-Scores in IIM

## Physician Global Disease Score



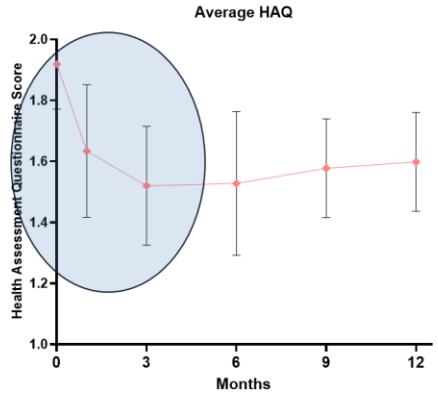

- Physician Global Disease Score is ranked from 0.0-10.0 cm
- **Continual decrease from baseline to month 6.**

## MMT-8



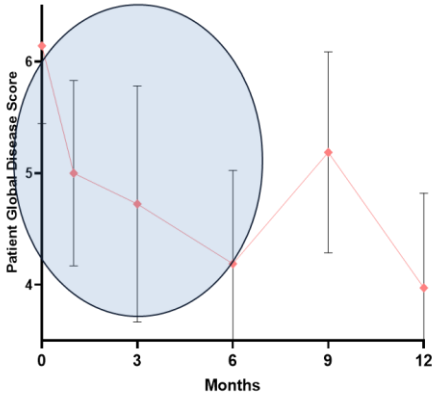

- Manual Muscle Strength testing Score is ranked from 0 - 80.
- **Initial improvement is present and maintained through month 12.**

## Health Assessment Questionnaire



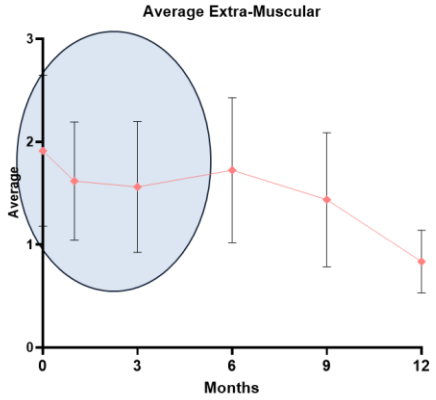

- Health Assessment Questionnaire Score is ranked from 0 - 3
- **Continual decrease from baseline to month 3 and maintained through month 12.**

## Patient Global Disease Score



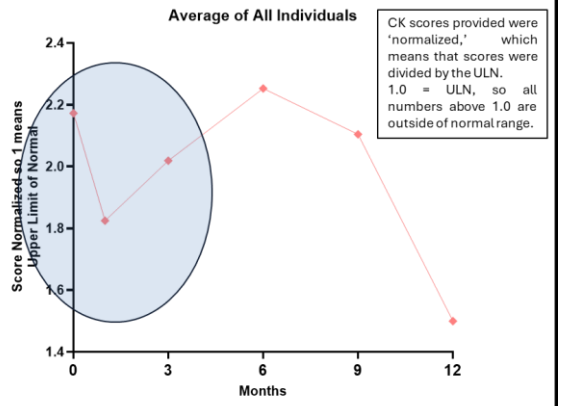

- Patient Global Disease Score is ranked from 0.0-10.0 cm
- **Continual decrease from baseline to month 6.**

## Extra-muscular




- Extra-Muscular Score is ranked from 0 -10 cm
- **Initial improvement is present and continual decrease from baseline through month 12.**

## Creatine Kinase (Enzyme)




- Creatine Kinase (CK) upper limit of normal for women is 200 U/L and for men is 320 U/L
- **Initial improvement is present and ultimately tending to decrease from baseline to month 12**

* Pt 3 did not return for 12-month visit

** Pt 7 was excluded from these graphs due to a symptomatic flare that required significant steroid redosing, thus distinguishing this patient from all other participants in the trial.



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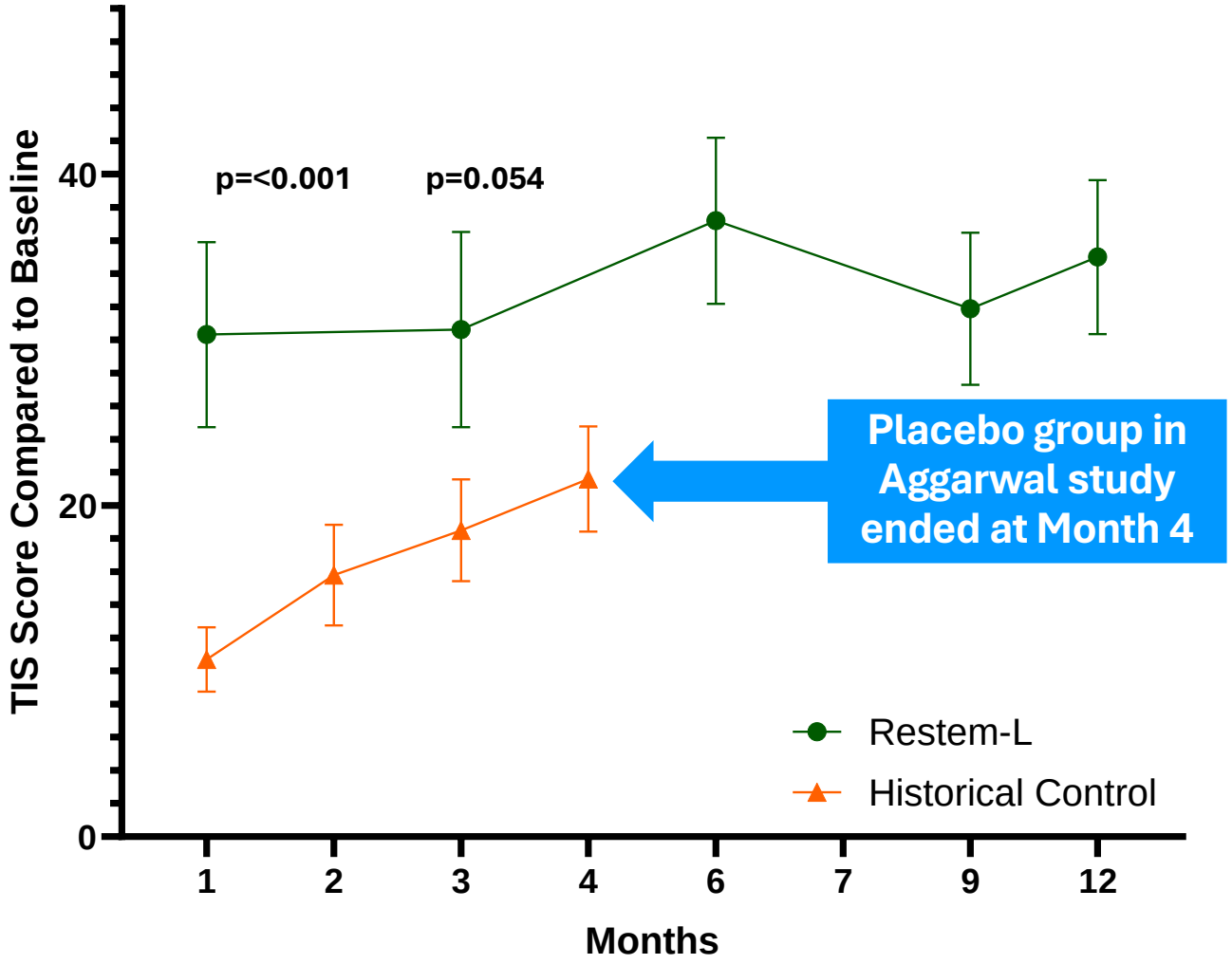
# IIM (DM/PM) Phase 1 Trial Results vs Historical Placebo




- Placebo group from the Aggarwal study provides natural history data (orange)*
- Restem-L Phase 1 study demonstrated statistical significance

*Aggarwal, R., et al., *Trial of Intravenous Immune Globulin in Dermatomyositis*. N Engl J Med, 2022. **387**(14): p. 1264-1278



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# Summary of IIM Phase 1 Study Results

## Data featured in an oral presentation at the American College of Rheumatology's (ACR) 2024

Completed Phase 1 study in 9 patients with PM/DM, showed **safety** and **preliminary efficacy** with **no serious adverse events**

Clinically **Significant Improvements** observed in **78%** of the patients (7 out of 9)

Average Total Improvement Score **(TIS) of 30-35%** in all patients **achieved within 1 month** of treatment and **maintained over 1 year** *(well above the FDA-established 20% TIS meaningfulness improvement standard)*

**~50% reduction** in daily steroid usage within 6 months of a **single** treatment while **concurrently improving** symptoms

Supported by the strong clinical trial data, the FDA granted Restem-L **Fast Track** and **Orphan Drug Designations** in IIM



https://acrabstracts.org/abstract/safety-and-efficacy-data-from-a-phase-i-trial-of-umbilical-lining-derived-stem-cells-ulsc-in-adult-dermatomyositis-polymyositis/

# *IIMPACT* - FDA-Authorized Phase 2/3 in IIM, a Potentially Registrational Trial

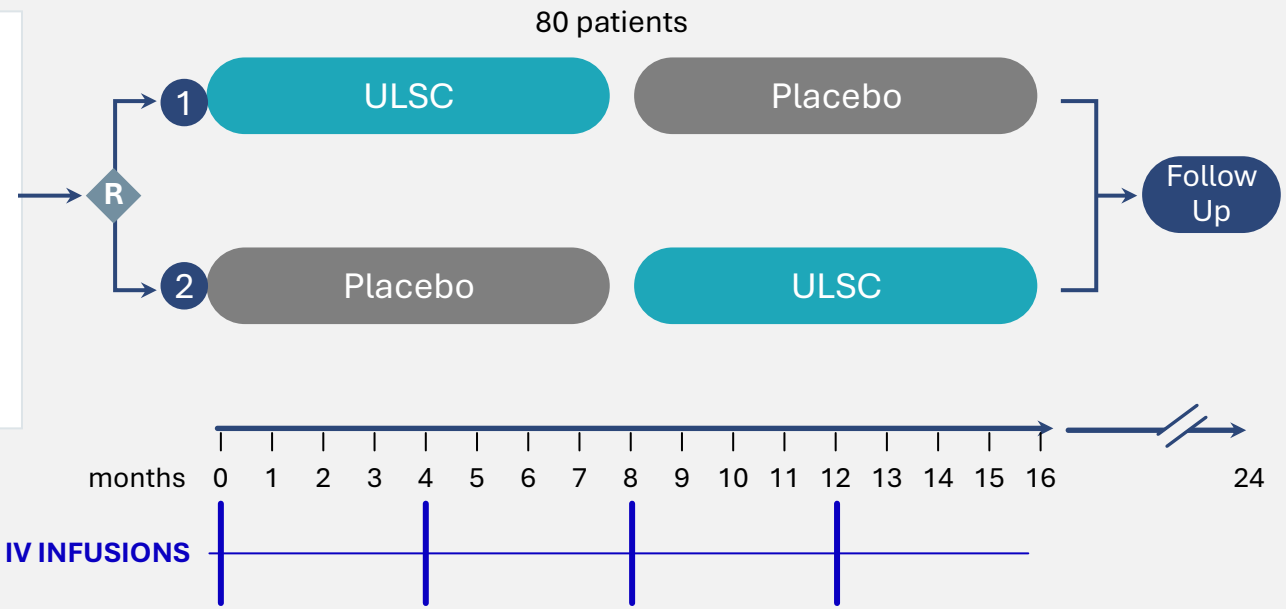
## Pivotal, Adaptive double-blinded, randomized, dose-repeating, crossover study

### Inclusion Criteria

≥18 years old with diagnosis of PM/DM based on EULAR/ACR score and Active Disease;

Participants must be receiving stable treatment, with one or more oral immunosuppressant medications, HCQ, and/or corticosteroids

### Treatment Arms




### Endpoints

Total Improvement Score (TIS), from baseline and by comparison with placebo;

Pre-specified steroid step-down to solidify the finding of the concurrent efficacy and steroid reduction

**Institution / Investigator**: Veterans Affairs Medical Center / Michael Bubb, MD (Principal Investigator)



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# Restem-L in Ulcerative Colitis

## Ulcerative Colitis (UC)

UC is a chronic, inflammatory autoimmune condition characterized by relapsing and remitting mucosal inflammation, starting in the rectum and extending proximally; in severe cases, UC can involve the entire colon

## Unmet Medical Needs

In 2024, there are ~1 M diagnosed adult UC patients in the US

UC can cause life-threatening complications (CRC, fulminant UC, perforation of the large intestine) and impactful side effects (severe anemia and dehydration, osteoporosis)

## Cost and Current Treatment

UC treatment options are non-curative; biologics are used as a first- or second-line option to treat patients with moderately to severely active UC with yearly costs ranging from $51,000-$180,000

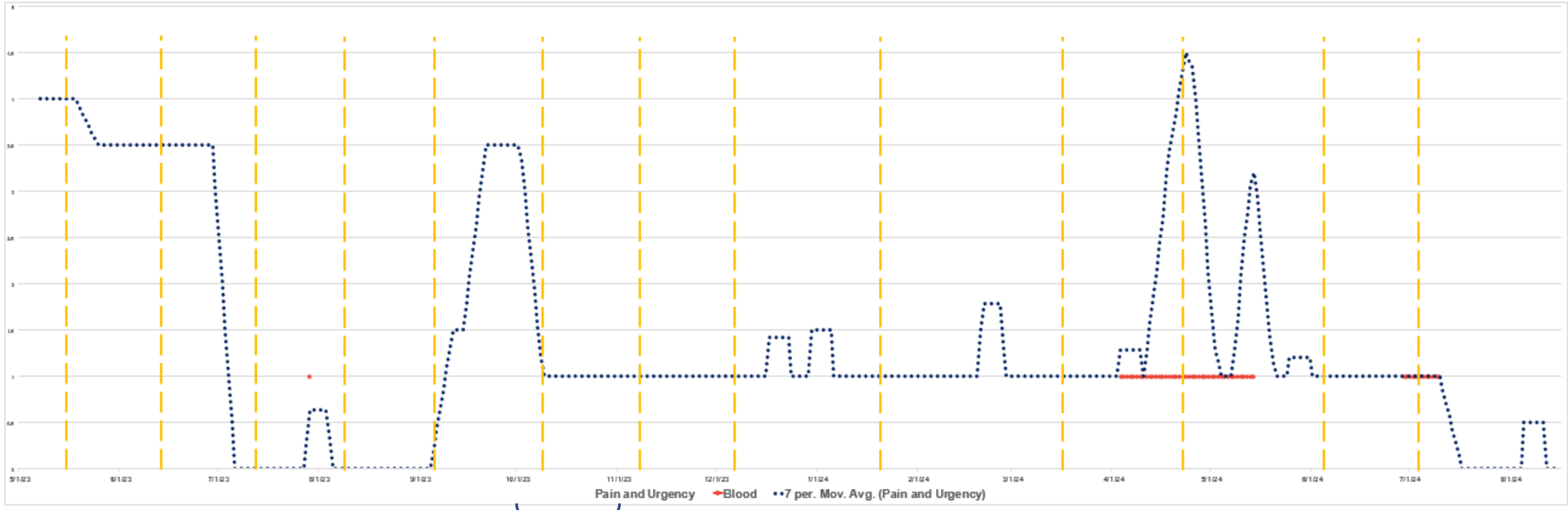
## Restem-L Potential

Encouraging eIND data of treated UC patient suggests Restem-L may provide an effective and safe treatment option in later-line or refractory patients that have exhausted other treatment options or do not respond to standard-of-care therapies

*Note: Average volume of diagnosed UC cases was calculated for sources reporting a range of diagnosed prevalence rates : Lewis, et al, Weisman, et al, Shivashankar, et al, Kappelman, et al

CRC: colorectal cancer

# eIND UC Patient Data (Infliximab-Only Treatment Graph)




5/1/2023

One-month intervals

8/16/2024

- Chart showing symptoms of **PAIN & URGENCY**, and **BLEEDING** for Ulcerative Colitis patient
- **YELLOW** lines represent each infusion of current standard of care medication (Infliximab)
- **No association of infliximab with symptom improvement**



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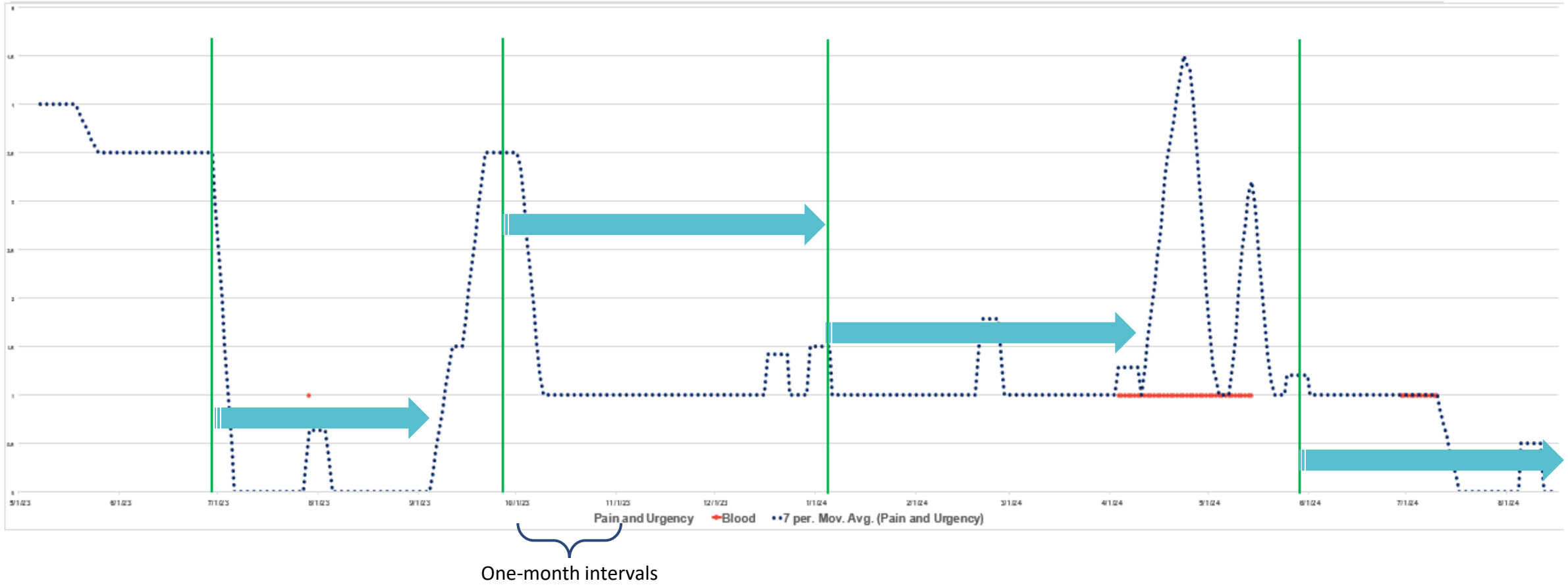
# eIND UC Patient Data (Restem-L-Only Treatment Graph)




- Chart showing symptoms of **PAIN & URGENCY**, and **BLEEDING** for Ulcerative Colitis patient
- **GREEN** lines represent intravenous infusions of 100 million ULSC provided under eIND
- **Prolonged remissions following treatments with Restem-L suggests symptomatic improvement**



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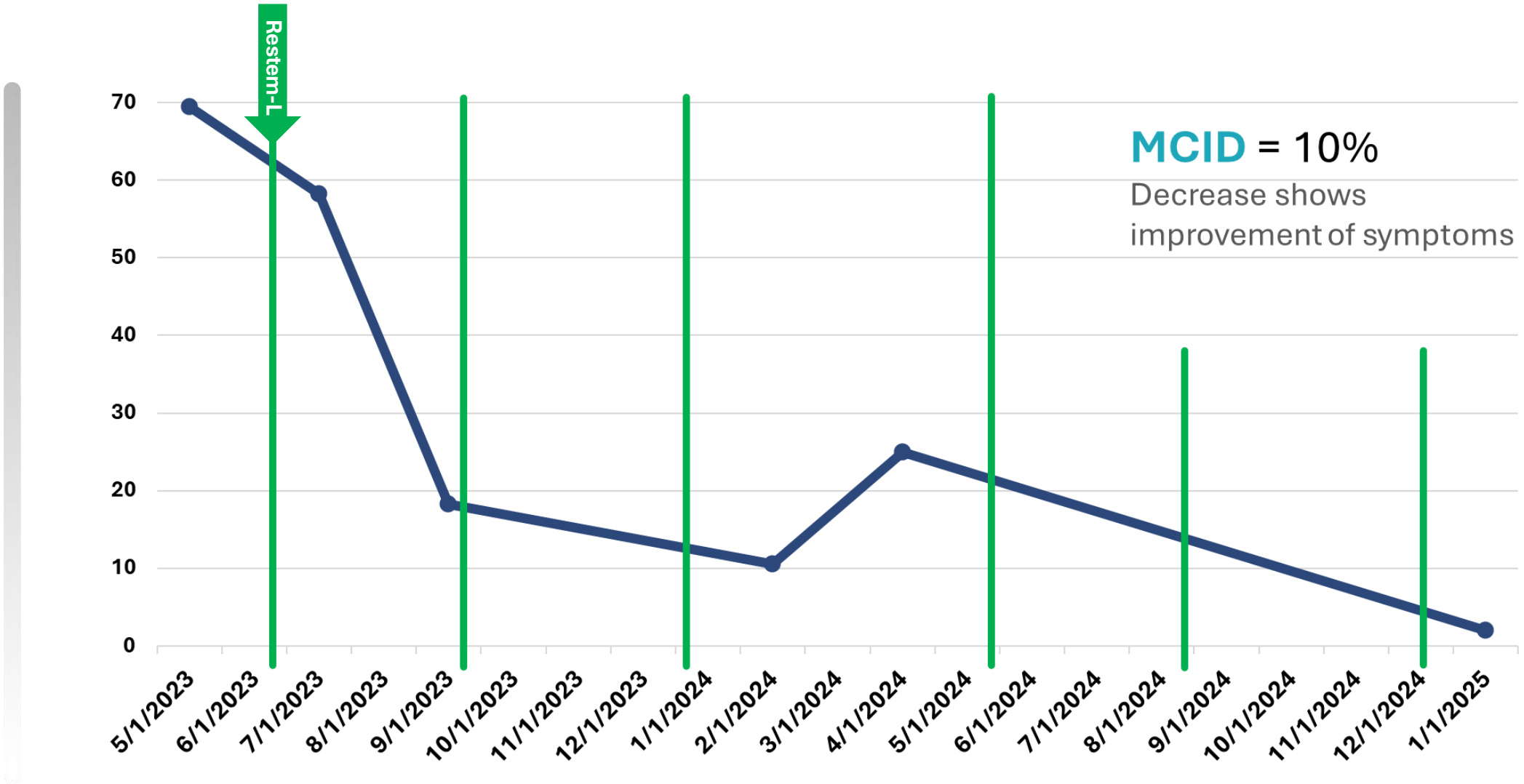
# eIND UC Patient Data

## IBSQOL Questionnaire Scores: 2023 - Present




**Irritable Bowel Syndrome Quality of Life Instrument (IBS-QOL)**

A condition-specific measure for assessing health-related QoL among persons with irritable bowel syndrome.



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# Restem-L in Rheumatoid Arthritis

## FDA Authorization for Phase 2 IND

### Rheumatoid Arthritis (RA)

Rheumatoid Arthritis is a chronic, autoimmune disease of unknown etiology that primarily affects synovial joints.
In RA, dendritic cells and macrophages release cytokines that promote the differentiation of naïve helper T cells while suppressing regulatory T cell production

### Unmet Medical Needs

In 2024, there were ~1.65 M diagnosed adult RA patients in the US*; 20-30% of RA patients are refractory**
RA significantly impacts QOL contributing to physical disfunction, disability, chronic pain, and fatigue

### Cost and Current Treatment

While there is no cure for RA, current treatments, such as chronic steroids and disease-modifying anti-rheumatic drugs (DMARDs), may help slow disease progression. Approximately 60% of patients require biologics, with annual costs ranging from $80,000 to $120,000

### Restem-L Potential

Promising IIM data strengthens confidence in RA success as a T-cell-mediated disease. Restem-L may provide sustained efficacy with a favorable safety profile by modulating key inflammatory factors, including TNFα, IL1β and IL6 , which play a major role in RA.

*Note: Average volume of diagnosed RA cases was calculated for sources reporting a range of diagnosed prevalence rates : Hunter, et al, Myasoedova, et al, Almutairi, et al
** www.arthritis.org/news/stories-of-yes/dr-daniel-solomon-researching-refractory-ra.



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# All Clinical Indications - Restem-L

| INDICATION | PARTICIPANTS | DOSES |
|---|---|---|
| DM-PM *(Phase 1)* | 9 | 9 |
| CHF *(Phase 1)* | 9 | 9 |
| COVID *(Phase 1)* | 17 | 23 |
| COVID *(eINDs)* | 9 | 9 |
| HLH, SL *(eIND)* | 1 | 1 |
| Graft v. Host, SG *(eIND)* | 1 | 2 |
| Pulmonary Fibrosis, GK *(eIND)* | 1 | 4 |
| Interstitial Lung Disease, BM *(eIND)* | 1 | 1 |
| Autoimmune Hep, TC *(eIND)* | 1 | 6 |
| Neuromyelitis Optica, KL *(eIND)* | 1 | 1 |
| Ulcerative Colitis, AC *(eIND)* | 1 | 6 |
| Crohn's disease, JW *(eIND)* | 1 | 3 |
| **TOTAL** | **53** | **74** |

# Superb Clinical Safety Profile - Restem-L

## Positive safety profile across different types of diseases

| Adverse Reaction | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|
| ***Infusion Reactions:*** | | | | | |
| Anaphylaxis | 0 | 0 | 0 | 0 | 0 |
| Chills | 0 | 0 | 0 | 0 | 0 |
| Skin Reaction | 0 | 0 | 0 | 0 | 0 |
| Hyper/Hypotension | 0 | 0 | 0 | 0 | 0 |
| Flushing | **1** | 0 | 0 | 0 | 0 |
| ***CNS Reactions:*** | | | | | |
| Fatigue | 0 | 0 | 0 | 0 | 0 |
| Confusion | 0 | 0 | 0 | 0 | 0 |
| Headache | 0 | 0 | 0 | 0 | 0 |
| ***Nausea*** | 0 | 0 | 0 | 0 | 0 |
| ***Cardiopulmonary reactions*** | 0 | 0 | 0 | 0 | 0 |
| ***Gastrointestinal Reactions*** | 0 | 0 | 0 | 0 | 0 |
| ***Infection*** | 0 | 0 | 0 | 0 | 0 |
| ***Thromboembolic Events*** | 0 | 0 | 0 | 0 | 0 |
| ***TOTAL*** | **1/74** | **0/74** | **0/74** | **0/74** | **0/74** |



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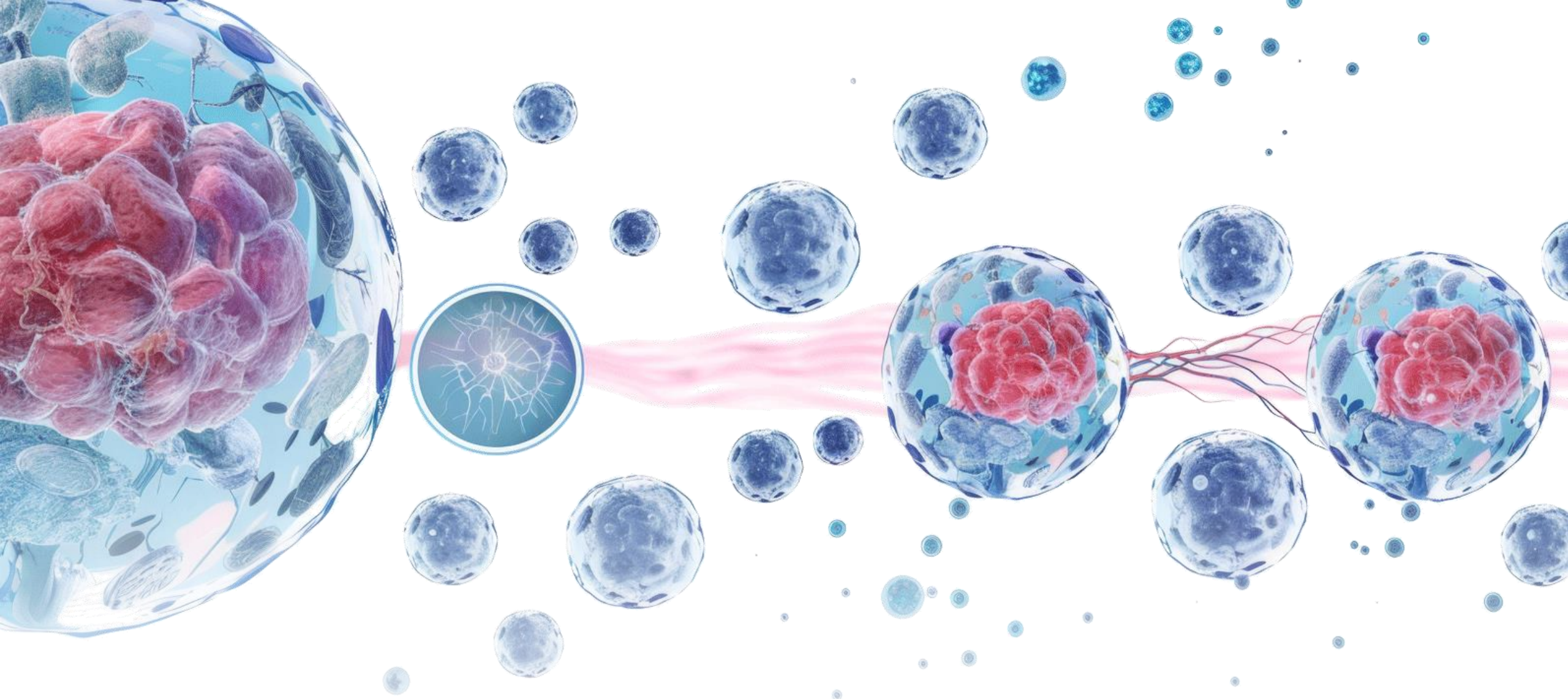


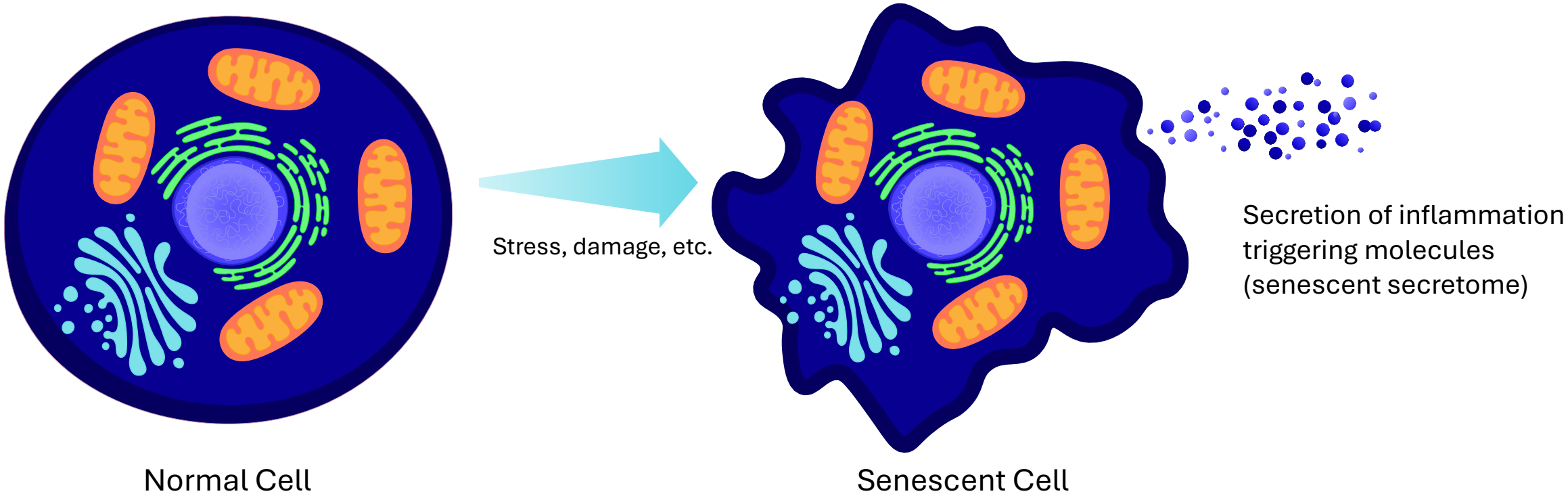
RESTEM

# Activated Natural Killer Cells: Reducing the Burden of Senescent Cells

# Senescent Cells

Aging is marked by damage caused by senescent cells, which cease to divide and occupy space without undergoing self-destruction

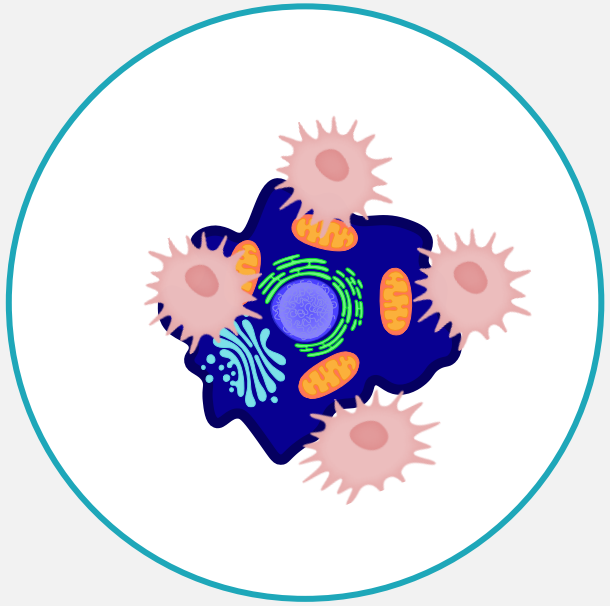
This accumulation impairs tissue removal and disrupts local homeostasis






RESTEM

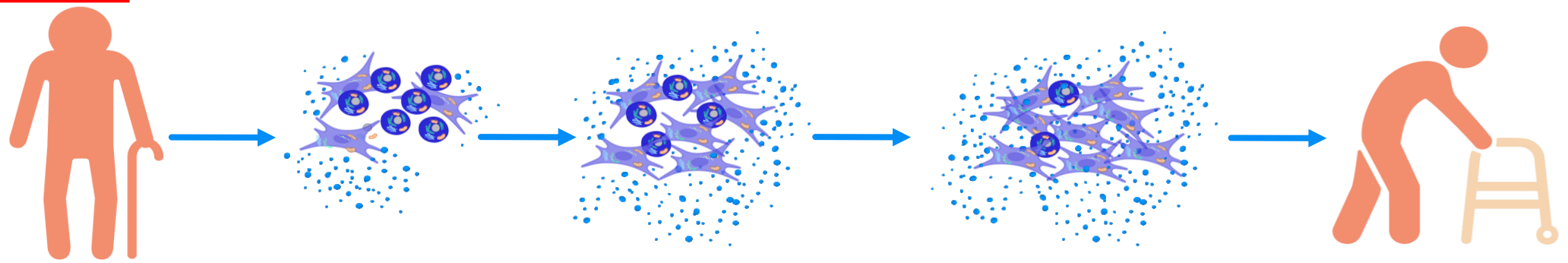
# aNK Targets Immunosenescence



- ✓ Our *activated* Natural Killer (aNK) cells are proprietary immune cells specifically enhanced to recognize and eliminate senescent cells which may reverse age associated diseases
- ✓ Patented methods to isolate, purify, expand and activate NK cells
- ✓ Restem is only company harnessing the power of NK cells to target and reverse cellular senescence

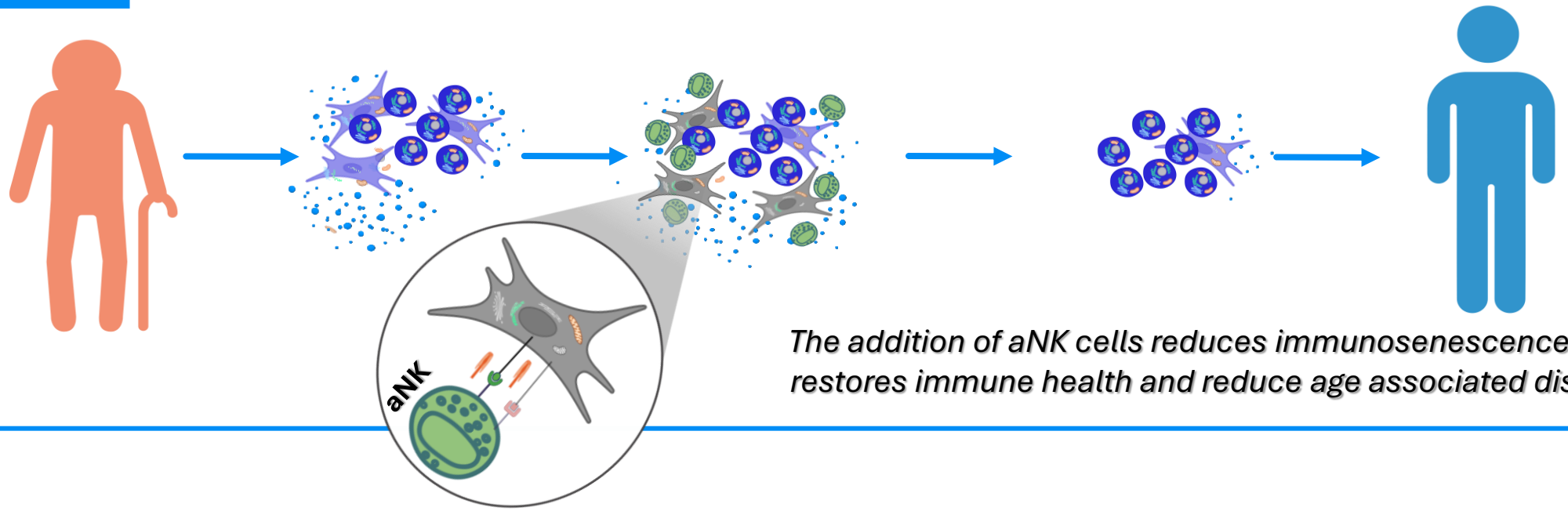
# Activated Natural Killer (aNK) Cells Reduce Immunosenescence

## Untreated Aging



*Senescent cells generate multiple factors that disrupt other cells causing cancer, heart disease and neurodegenerative disorders*

## Treated Aging



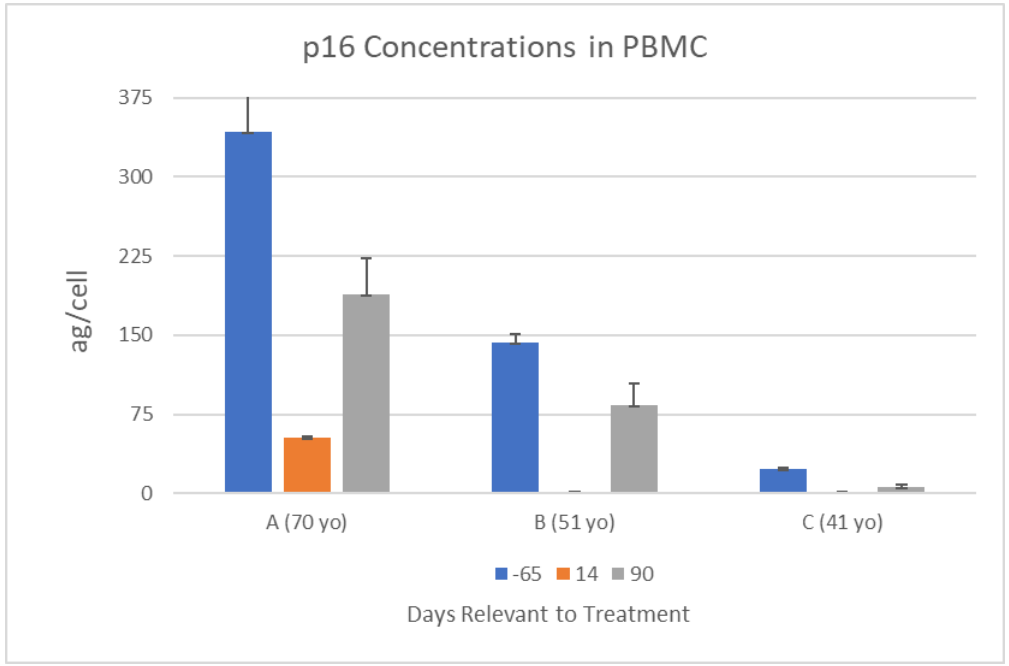

*The addition of aNK cells reduces immunosenescence which restores immune health and reduce age associated diseases*



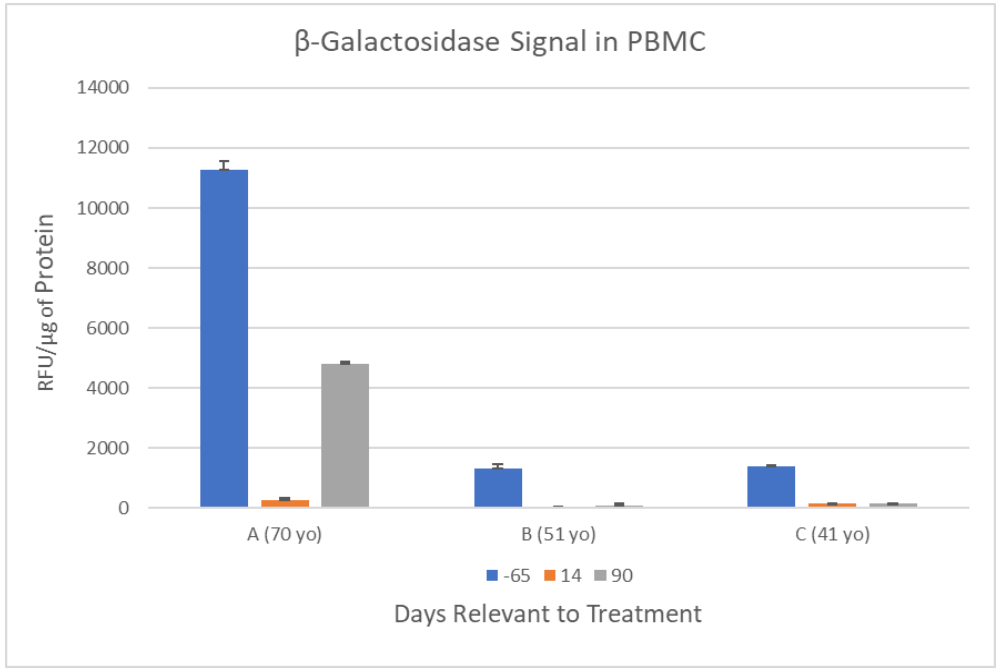
RESTEM

# Effects of aNK on Senescence Markers in Patients

## aNK treatment significantly reduced key senescence markers (p16 and β-gal) in PBMCs isolated from donors




Significant reduction in p16 levels, post aNK treatment




Decrease in β-gal activity in all donors, post aNK treatment

**These findings support the therapeutic potential of aNK in restoring immune function and targeting senescent cells in aging-associated diseases**



Chelyapov, Nickolas et al. "Autologous NK cells propagated and activated ex vivo decrease senescence markers in human PBMCs." Biochemistry and biophysics reports vol. 32 101380. 11 Nov. 2022,

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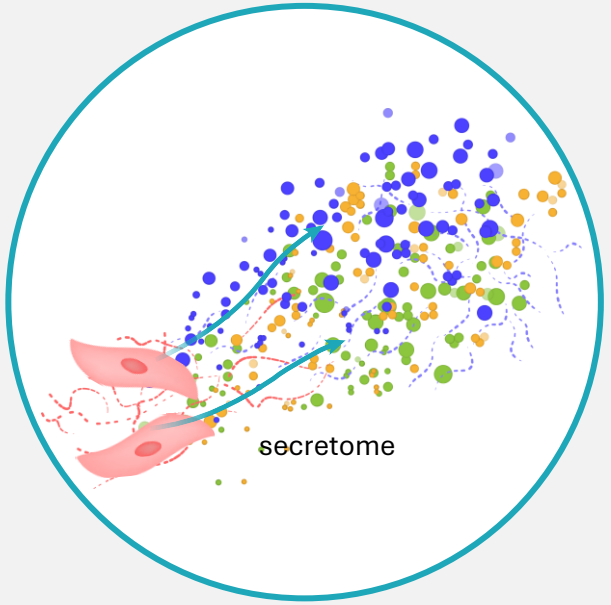
# Restem-X:
# A Regenerative Secretome

# Harnessing Restem-X




- ✓ Restem-X is a cell-based secretome derived from our proprietary Restem-L product
- ✓ Contains a diverse array of bioactive molecules, including growth factors, cytokines, and extracellular matrix proteins
- ✓ These bioactive molecules enhance cellular communication and promote tissue repair and regeneration
- ✓ Natural and safe therapeutic product



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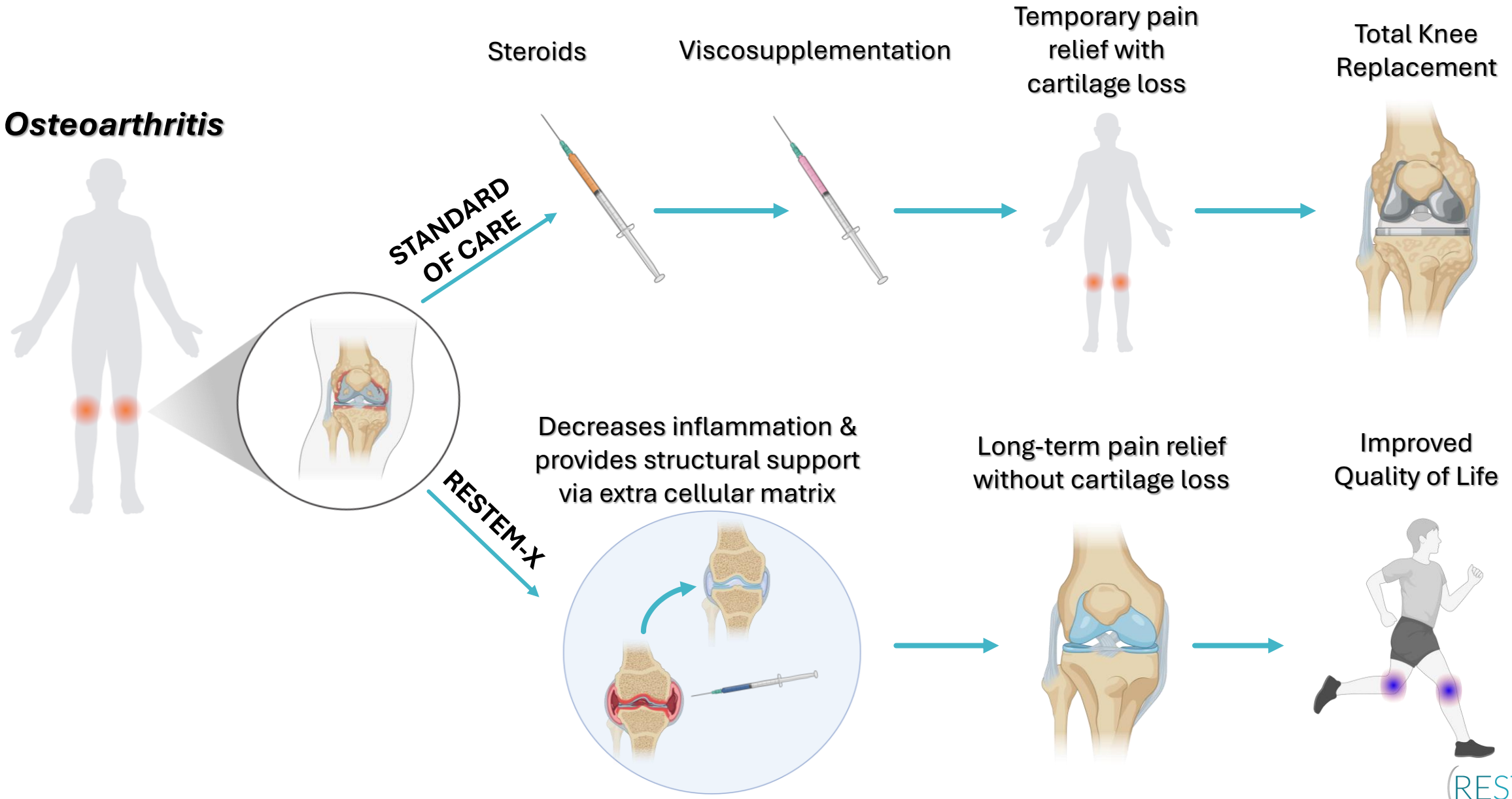
# Restem-X Modulates Inflammation and Provides Structural Support



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# Restem-X  Potential Applications in Orthopedics

## Supports Joint Health and Tissue Repair

- Contains key components for orthopedics, including hyaluronic acid (HA), interleukin-1 receptor antagonist (IL-1RA), and fibroblast growth factor 2 (FGF-2)
- Targets the root causes of osteoarthritis by addressing both inflammation and cartilage damage, leading to improved mobility and reduced pain
- Visco-supplementation market valuation of $5.12 billion in 2024*

| High MW HA | IL-1RA | FGF-2 |
|---|---|---|
| High Molecular Weight Hyaluronic Acid restores joint lubrication, improving knee function and reducing friction in osteoarthrosis | Interleukin-1 Receptor Antagonist (IL-1RA) reduces inflammation and cartilage degradation | Fibroblast Growth Factor-2 (FGF-2) stimulates tissue repair and regeneration, promoting recovery in damage joints |

**Robust potential for joint regeneration and pain management**



*https://www.globenewswire.com/news-release/2025/01/06/3004788/0/en/Global-Viscosupplementation-Market-to-Hit-Valuation-US-11-31-Billion-By-2033-Astute-Analytica.html

# Clinical Pipeline & Funding Plan

| | H1 2025 | H2 2025 | H1 2026 | H2 2026 |
|---|---|---|---|---|
| **Restem-L** | Start of Phase 2/3 in IIM | Start of Phase 2 in RA | | Interim Phase 2/3 data in IIM |
| **aNK** | Completion of allogeneic aNK & exosomal product | Submission of Phase 1 in Frailty | | Start of Phase 1 in Frailty |
| **Restem-X** | IND submission for Osteoarthritis (OA) | | Start of Phase 1 in Osteoarthritis | Interim Phase 1 data in OA |
| **Cash Runway** | **Closed Friends and Family** | | | |
| | | **Series A / Crossover $50M-$60M** | | |
| | **Secured non-dilutive funding for IIM Trial** | | | |



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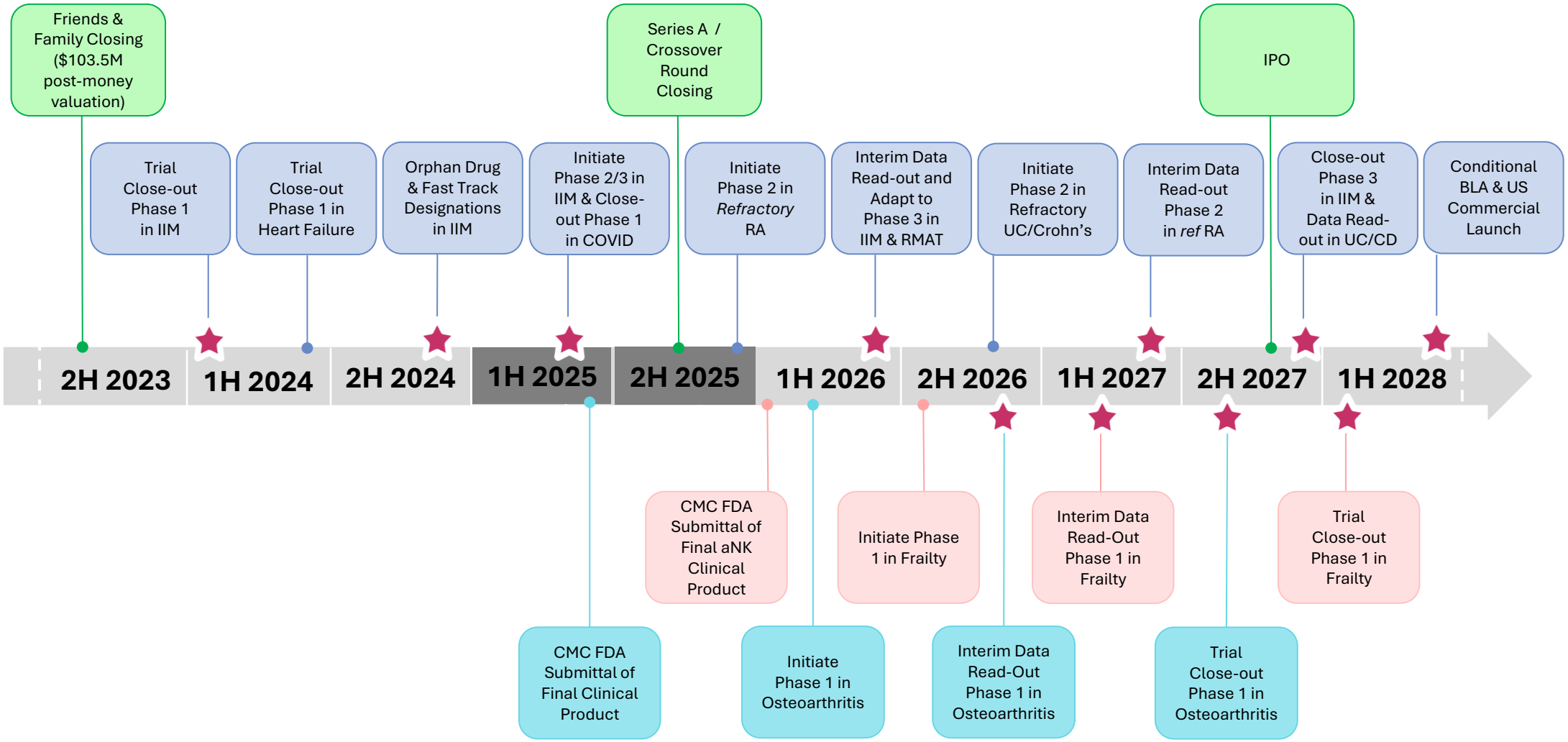
# RESTEM – Historical Milestones and Future Value Drivers



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# *Thank You*