



Advanced Critical Care With MultiStem Cell Therapy

Investor Overview



Forward Looking Statements

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Athersys Corporate Summary

- **Athersys is a clinical-stage biotech company focused on the next generation of therapies for critical health issues**
 - A leader in the field of allogeneic cell therapy, which expands cells from healthy donors into a cellular therapy that acts to minimize inflammatory damage following an injury and helps modulate healing of the damaged tissue.
 - Our technology, MultiStem, is protected by approximately 400 patents and we retain global rights to the technology (excluding Japan where we have a partner)
 - 20 years of research on this technology; 15 years of clinical trials; 450+ patients dosed with an excellent safety record
 - Leader in larger-scale manufacturing
- **We are focused on major markets with high unmet patient need, with upcoming near-term milestones**
 - **MultiStem is a platform technology** with significant preclinical data packages in areas including Graft vs Host Disease, Multiple Sclerosis, Traumatic Brain Injury
 - We are currently in advanced clinical development in three indications:
 - **Stroke: Phase 3 / pivotal trial** with anticipated data readout by Q2 2025; interim analysis targeted for October 2023
 - **Trauma: Phase 2 trial** sponsored by DoD, anticipated data read-out by 2025
 - **ARDS: Phase 3 / pivotal trial pending launch in Japan**
- **We are set up to succeed**
 - New and experienced management team
 - Lean operating model focused on achieving clinical milestones
 - Additional focus on spinning off non-core technologies, animal health cell therapy and cryo-storage technology
 - Pursuing additional global and regional partnerships to establish commercial expertise and networks



MultiStem: Proprietary Cell Therapy Platform



MultiStem® Cell Therapy Platform: Ethical, Versatile & Favorable Tolerability

Adult bone marrow-derived stem cells



Off-The-Shelf Product

Allogenic, no tissue matching, IV administration of up to 1.2 billion cells per dose



Scalability, Stability & Consistent Product Quality

Single adult donor capable of generating hundreds of thousands of doses in proprietary process
Manufacturing Quality ATMP Certification by EMA/CHMP



Several Late-Stage Clinical Trials, Safety Data in >450 Patients

Only ongoing Phase 3 cell therapy study in ischemic stroke, with RMAT, SPA and Fast-Track Regulatory Designations from FDA



Well-Characterized Mechanism of Action

Applicable Across Many High Value Indications



MultiStem Platform Advantages: Innovation From Donor to Patient




- A leader in larger-scale manufacturing development
- Over 10 years of successful GMP manufacturing with 170 batches and 1,100 doses produced
- One healthy human donor can be expanded to hundreds of thousands of clinical & commercial doses
 - 1.2 Billion cells / dose
- Product can be prepared and administered from pharmacy to patient in less than one hour



One Donor ➡ Master and Working Cell Banks ➡ Large Scale Cell Expansion in Bioreactors ➡ Hundreds of thousands of doses to treat patients

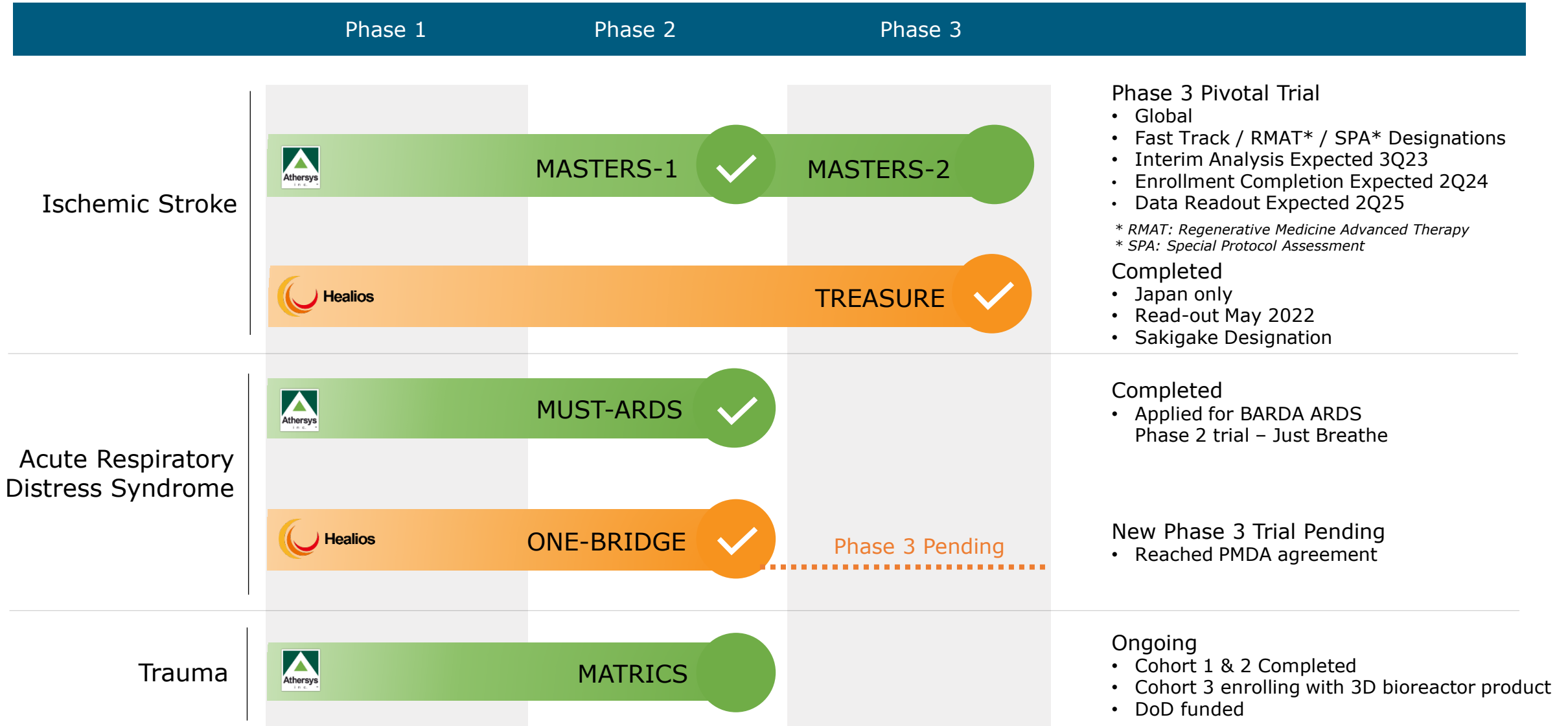


Lead Indications

	 Ischemic Stroke	 ARDS	 Trauma
Frequency	~800,000 strokes per year in the US	200,000 cases in the U.S. annually	3 million non-fatal injuries per year 150,000 deaths, and ~2/3 of trauma patients will experience SIRS (Systemic Inflammatory Response Syndrome)
Patient Impact	Leading cause of disability and third highest cause of death	Up to 50% mortality rate One of the leading causes of death in severe COVID cases	Leading cause of death in people under 40 in the U.S
Economic Burden	Over \$55 billion cost to the health care system annually	Leading cause of ventilation and ICU admission	The economic cost of trauma amounts to \$671 billion every year
Treatment Options	Current standard of care includes thrombolytics and mechanical thrombectomy, which reach only 30% of patients	Few effective therapeutic modalities exist to ameliorate this deadly condition	Limited effective treatment options for SIRS (Systemic Inflammatory Response Syndrome)
Addressable Population	43% of all strokes are moderate to severe ischemic strokes, the focus of our trial with MultiStem	MultiStem is currently being studied in patients with moderate-severe ARDS, 77% of the total ARDS population	We estimate that up to 70% of severe trauma patients admitted to the hospital could benefit from treatment with MultiStem



Significant Clinical Work in Targeted Indications





MultiStem® Cell Therapy Platform: Opportunities Across Serious Unmet Need Indications

PHASE 3	Ischemic Stroke	IND READY	Hemorrhagic Stroke	NONCLINICAL	Parkinson's Disease	NONCLINICAL	Rheumatoid Arthritis
PHASE 2	Trauma	IND READY ^E	Hypoxic Ischemia	NONCLINICAL	Alzheimer's Disease	NONCLINICAL	Congestive Heart Failure
PHASE 2/3	Acute Respiratory Distress Disorder	IND READY	Traumatic Brain Injury	NONCLINICAL ^G	Lysosomal Storage Disorders	NONCLINICAL	Peripheral Vascular Disease
PHASE 2/3 ^G	Graft vs Host Disease	IND READY ^E	Spinal Cord Injury	NONCLINICAL	Multiple Sclerosis	DEVELOPMENT	Animal Health: Canine
PHASE 2	Acute Myocardial Infarction	NONCLINICAL	Acute Radiation Syndrome	NONCLINICAL	Alcoholic Hepatitis	DEVELOPMENT	Animal Health: Equine
IND READY	Transplantation	NONCLINICAL	Epilepsy	NONCLINICAL	Wound Healing	DEVELOPMENT	Animal Health: Feline



Strengthened & Experienced Leadership

Broad Experience in Pharmaceutical & Life Science



Dan Camardo, MBA
Chief Executive Officer



Maia Hansen, MBA
Chief Operations Officer



Kasey Rosado
Interim Chief Financial Officer



Manal Morsy, MD, PhD, MBA
EVP, Regulatory Affairs



Robert (Willie) Mays, PhD
EVP, Regenerative Medicine



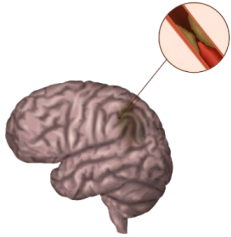


Ischemic Stroke

Overview
Unmet Medical Need
MultiStem Clinical Trials

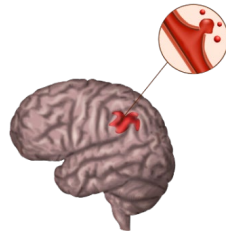
Stroke Overview

Background



Ischemic Stroke

Caused by a blocked artery



Hemorrhagic Stroke

Caused by leaking or bursting of a blood vessel



A stroke occurs when the blood supply is interrupted or reduced to part of the brain. This prevents brain cells from getting oxygen and nutrients, leading to cell death and tissue loss



Stroke is the **leading cause of disability** and the **third leading cause of death** in the US



Each year nearly **800,000** people in the US suffer a stroke



About **43%** of all strokes are **moderate to severe ischemic strokes**, the focus of our trial

Impact



High Unmet Need

Only 30% of patients qualify for current standard of care (thrombolytics / mechanical thrombectomy) both of which have limited treatment windows and patient eligibility



High Burden on Healthcare System

Stroke patients have a \$55 billion impact on the healthcare system



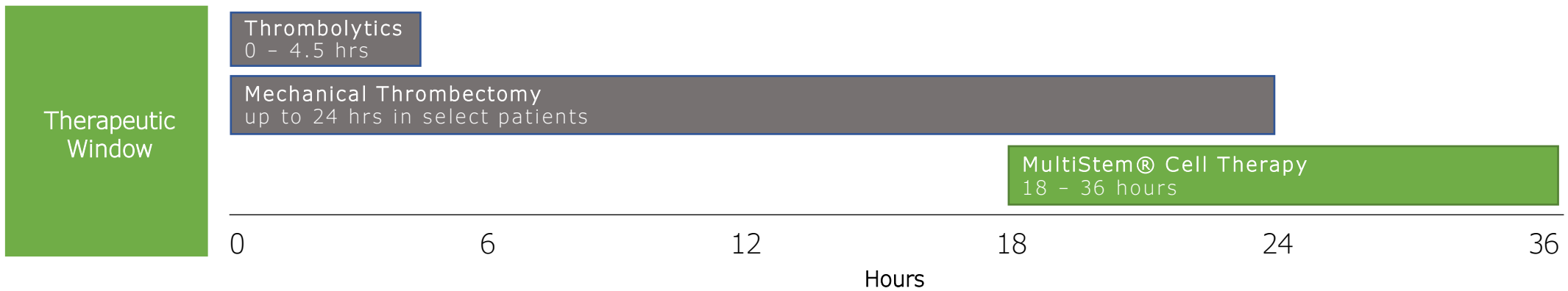
MultiStem Solution

- Expands treatment window to 36 hours
- Potential to provide additive benefit to standard of care
- Treats bodily response to clot formation and prevents secondary injury and complications caused by the stroke



Unmet Medical Need in Stroke: Only 2 Approved Ischemic Stroke Treatments




	Thrombolytics	Mechanical Thrombectomy	MultiStem® Cell Therapy
Mechanism of Action	Clot dissolving medications	Removal of the clot using a catheter device	Modulation of the immune system
Applicability	Only 15% of ischemic stroke patients are eligible for tPA within 4.5 hours	Only ~10% of ischemic stroke patients are eligible due to the location of the clot	Potentially applicable to 90 - 95% of all ischemic stroke patients because of extended therapeutic window and mechanism of action
Benefit	Improved recovery in ~15% of patients who receive tPA at 90 days with little additional improvement at Day 365	Improved recovery comparable to tPA at 90 Days with no clinically meaningful improvement from 90-365 Days	Promotes recovery, projected clinically meaningful benefit. Can be given independently or following thrombolytics and/or thrombectomy at both 90 Days and 365 Days
Safety / Complications	Associated with hemorrhagic transformations in 2 - 4% of patients	Potential vascular damage and cerebral edema	2 completed studies and 3 rd ongoing with a favorable tolerability profile





Clinical Trials

MultiStem for Ischemic Stroke

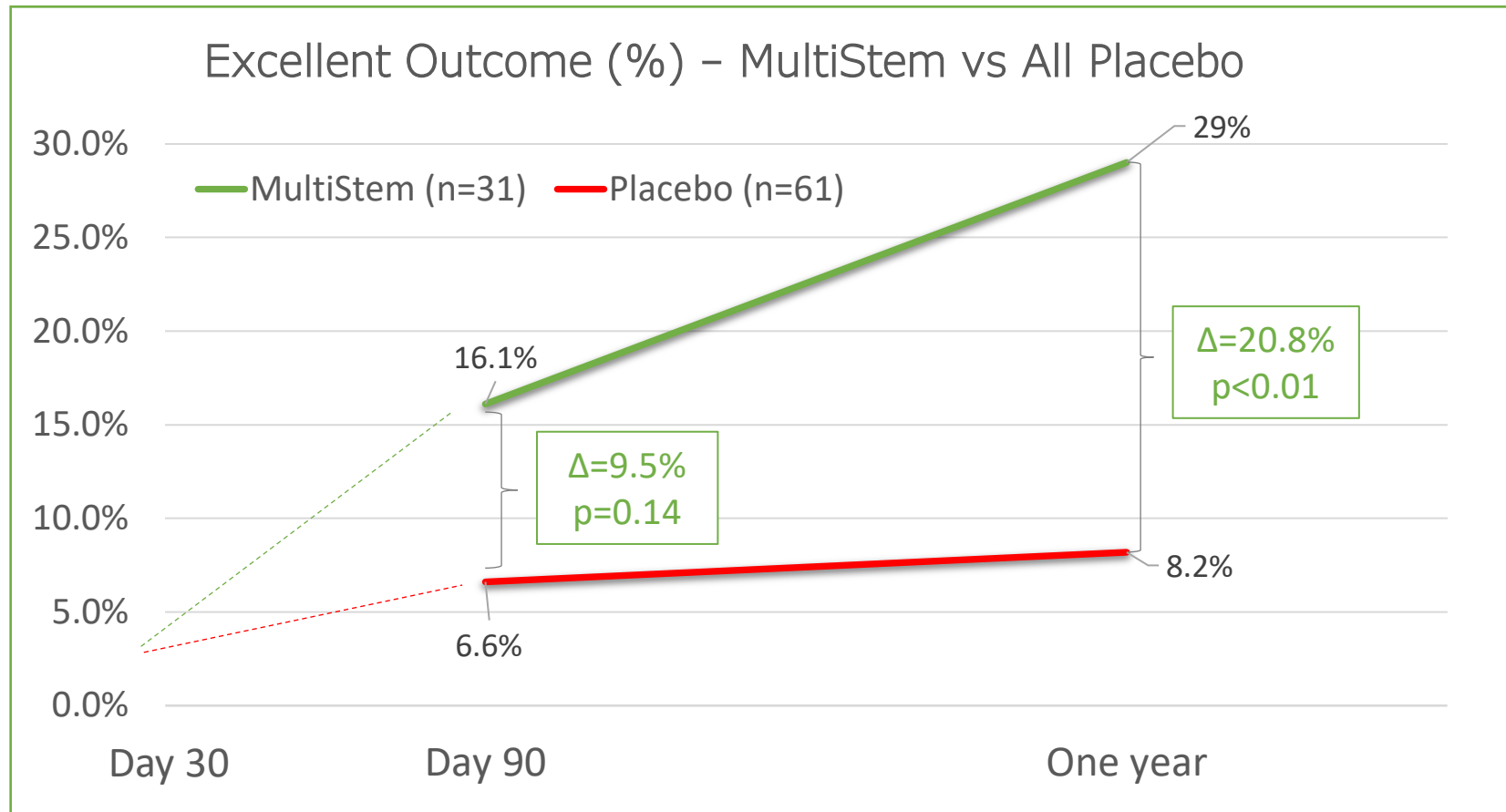
	 MASTERS-1	 TREASURE (Healios)	 MASTERS-2
Phase - # Subjects	Phase 2 - 126 subjects	Phase 2/3 - 206 subjects	Phase 3 - 300 subjects
Date Conducted	2010 - 2016	2017 - 2022	2018 - Present
# Sites - Countries	33 - US, UK	48 - Japan	39 - US, UK, EU, Taiwan, Australia
Endpoints	Primary - Global stroke recovery at day 90	Primary - Excellent Outcome at day 90	Primary - mRS shift at 365 days
Results	<ul style="list-style-type: none">• Primary Endpoint missed• Subset of patients who received MultiStem within 36 hours saw improvement in:<ul style="list-style-type: none">• Excellent Outcome, $\Delta=20.8\%$, $p<0.01$ at day 365• mRS shift analysis, $p=0.07$ at day 365	<ul style="list-style-type: none">• Primary Endpoint missed• Patients who received MultiStem saw improvement in:<ul style="list-style-type: none">• Global Recovery at day 365: $\Delta=12.2\%$, $p<0.05$• Barthel Index ≥ 95 at day 365: $\Delta=13.1\%$, $p=0.05$	<ul style="list-style-type: none">• Interim analysis expected to take place Q4 2023• Full enrollment expected Q2 2024• Data readout expected Q2 2025
Key Takeaways	<ul style="list-style-type: none">• Identified optimal time of administration (24-36 hours)	<ul style="list-style-type: none">• Confirmed optimal time of administration• Confirmed that cells convey long term meaningful benefit beyond 90 days• Observation that Excellent Outcome is a challenging primary outcome in aged population	<ul style="list-style-type: none">• Ongoing



MASTERS-1: Phase 2 Ischemic Stroke Trial Results

Treatment with MultiStem Shows Meaningful Benefit

Proportion of Subjects Treated within 36 Hours Achieving **Excellent Outcome** Increases Over Time
(Excellent Outcome = Patients Achieving NIHSS 0 or 1 and mRS 0 or 1, and Barthel Index ≥ 95)



Safety: Intravenous MultiStem **well-tolerated** by stroke patients, with no serious adverse reactions



Validation: Based on MASTERS-1 data, the stroke program was granted **Fast Track** and **RMAT designation** from the FDA



TREASURE Study by HEALIOS KK in Japan

Topline Data Announced May 2022 and Full Data in October 2022

- ✓ Sakigake designation
- ✓ 206 patients with moderate-to-moderate-severe strokes
- ✓ 48 trial sites in Japan
- ✓ Single cell therapy dose (1.2B cells) delivered intravenously within 18-36 hours following stroke onset or last known normal
- ✓ Informed KOL panel and FDA Type B meeting to ensure that full potential benefit of MultiStem therapy is captured in our Phase 3 trial

Favorable results at one year in recovery measures

- Indicates achievement of functional independence
- Reflects clinically relevant recovery in MultiStem® treated patients compared to placebo patients

One Year	MultiStem	Placebo	p-value*
Excellent Outcome	15.4%	10.8%	n.s.
Global Recovery	27.9%	15.7%	p<0.05
Barthel Index >=95	35.6%	22.5%	p=0.05

Excellent Outcome = mRS≤1, NIHSS≤1 and Barthel Index≥95

Global Recovery = mRS≤2, NIHSS Δ ≥75% and Barthel Index≥95

* Prespecified covariance adjustment based on stratification factors



Ischemic Stroke (MASTERS-2)

Ongoing Pivotal Phase 3 Study



Randomized, double-blind, placebo-controlled clinical trial, actively enrolling up to **300 patients in leading stroke centers** in U.S. and internationally, under SPA agreement



IV administration of 1.2 billion MultiStem® cells or placebo; based on successful results from Phase 2, treatment window moved earlier to **18 - 36 hours** after stroke onset



New Perspective – TREASURE data offered a unique opportunity to reevaluate MASTERS-2 trial design by leveraging the collective data of MASTERS-1 and TREASURE



Successful FDA Type B meeting resulted in 4 modifications:

- Primary efficacy endpoint: Modified Rankin Scale (**mRS**) **Shift from day 90 to day 365**
- **Removed all eligibility caps** on concomitant reperfusion therapy (e.g., tPA, MR or tPA+MR) to reflect current standard of care
- Added option for **interim analysis** to assess sample size
- **Reordered several secondary endpoints** to prioritize Day 365



Interim analysis projected for October 2023

Full enrollment projected in 2Q 2024

Data read out projected in 2Q 2025



Trauma

Overview
MultiStem Clinical Trials

Trauma Overview

Background



Trauma is the **leading cause of death** for people under the age of 45 and the leading cause of **quality-of-life years lost**



In the US, trauma accounts for over **150,000 deaths** and over **3 million** non-fatal injuries per year



Approximately **2/3 of trauma patients will experience SIRS** (Systemic Inflammatory Response Syndrome)

- 35% of all trauma patients that undergo hemorrhagic resuscitation die, patients that survive are then more likely to die of SIRS
- **SIRS** is a response of the peripheral immune system which leads to **secondary immune-mediated damage**



Impact



The economic cost of trauma amounts to **\$671 billion every year**, including health care and work loss for those suffering both fatal and nonfatal injuries



Treatments are needed to modulate the inflammatory system to reduce the risk of SIRS, which may lead to further complications and organ injury



Preclinical data supports that **MultiStem may prevent tissue related injury and immune cell overactivation** that follows traumatic injury, potentially mitigating SIRS



Trauma: Heterogeneity in Cause, Impact and Severity

Initial traumatic injury can result in SIRS related complications such as:

- Acute Kidney Injury (AKI)
- Acute Lung Injury
- ARDS
- Multiple Organ Failure
- Secondary Infection
- Sepsis
- Venous thromboembolism (VTE)
- Other secondary injury (e.g., cerebral edema)

Extensive Supporting Preclinical/Clinical Work




- Acute pulmonary injury
 - Porcine models demonstrate improvement in lung function from treatment with MultiStem
 - Multipotent adult progenitor cells decrease cold ischemic injury in ex vivo perfused human lungs. (La Francesca S, 2014)
 - MUST-ARDS and ONE-BRIDGE clinical studies
- Traumatic Brain Injury
 - MultiStem treatment improves neurologic recovery in rat TBI models (Bedi 2013, Bedi 2018)
- Spinal Cord Injury
 - Cell treatment promotes spinal cord tissue sparing and significantly improve urinary and locomotor recovery in rats with moderate/severe thoracic SC contusion (DePaul 2015)
- Kidney Injury
 - MultiStem administration to ischemia/reperfusion injured ex-vivo perfused human kidneys reduced IL-6 (inflammatory biomarker) and NGAL (kidney injury biomarker) and improved tissue perfusion defects and urine output (Thompson, 2020)
- Stroke
 - Dose dependent recovery in rat models with MultiStem treatment
 - MASTERS-1, TREASURE, MASTERS-2



MATRICS

Ongoing Phase 2 Study



-  Randomized, double-blind, placebo-controlled clinical trial, evaluating MultiStem in **156 patients** following resuscitation from hemorrhagic trauma
-  Underway at The University of Texas Health Science Center at Houston (UTHealth Houston) and Memorial Hermann-Texas Medical Center, **the busiest Level 1 Trauma Center in the U.S.**
-  Trial funding provided by MTEC (Department of Defense) and the Memorial Hermann Foundation
-  **IV administration** of 1.2 billion MultiStem® cells or placebo given 0-24 hours after initial injury
-  Complete enrollment has been reached in the second cohort in which patients were dosed with MultiStem cells manufactured under Athersys' new 3D manufacturing process
Enrollment in the third and final cohort initiated June 2023



Acute Respiratory Distress Syndrome (ARDS)

Overview
MultiStem Clinical Trials
Value Drivers

Background



ARDS occurs when inflammation effects the lungs, often as a result of **infection (such as COVID-19)** or **trauma**



~200,000 cases in the U.S. annually + ~2.2 M globally



Up to 50% mortality rate, one of the leading causes of death from COVID-19



Impact

No currently approved therapies for ARDS




Extended, **intensive hospitalized care** in ICU, where most patients are placed on **mechanical ventilation** to help them breathe, often requiring sedation

Patients face a possibility of **organ failure**, **serious lung damage**, and serious, sometimes lasting, **psychological effects** such as PTSD, depression, and anxiety

MultiStem represents a **high value intervention** which may reduce direct costs and increase productivity and quality-adjusted life years gained over the ARDS survivor's lifetime



Clinical Trials MultiStem for ARDS

	 MUST-ARDS	 ONE-BRIDGE	 Phase 3 Pending
Phase - # Subjects	Phase 1/2 - 36 subjects	Phase 2 - 35 subjects	Phase 3, pending, 80
Designation	RMAT, Fast Track	Orphan Designation	Orphan Designation
Date Conducted	2015 - 2019	2019 - 2021	TBD
Countries	US, UK	Japan	Japan
Endpoints	<ul style="list-style-type: none">Frequency of sustained hypoxemia or hypotension (4 hours) and;Suspected Unexpected Serious Adverse Reactions (SUSARs) within 24 hours of administration	<ul style="list-style-type: none">Ventilator-free days (out of 28)Mortality (at day 90)	<ul style="list-style-type: none">In development
Results	<ul style="list-style-type: none">Primary endpoints were met; MultiStem was well tolerated throughout the 4-hour observation period and no adverse events of special interest occurred. There were no SAEs throughout the one-year study causally related to MultiStemDose escalation up to 900 million cells	<ul style="list-style-type: none">MultiStem patients experienced lower mortality, fewer days on the ventilator, and less days in the ICUTreatment was well-tolerated with no serious adverse events900 million cells dosage	<ul style="list-style-type: none">Ongoing trial slated to use 3D bioreactor material1.2 billion cells dosage

Selected as finalist for the Biomedical Advanced Research and Development Authority's (BARDA) ARDS Therapeutics Pitch Event, Just Breathe



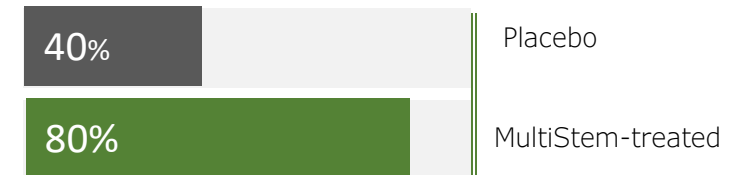
MUST-ARDS: Results from Exploratory Clinical Study in ARDS

All Subjects (in efficacy cohort)	MultiStem	Placebo
Number of Patients	20	10
Ventilator-free days (median)	18.5	6.5
Mortality (d28)	25%	40%

Patients w/ Low pulmonary function: PaO ₂ /FiO ₂ < 150 mm at baseline	MultiStem	Placebo
Number of Patients	8	8
Ventilator-free days (median)	18.5	3.5
Mortality (d28)	25%	50%



Patients who rated complete independence in self care at 1 year



Substantially **improved quality of life** over one-year follow up and improvements in patient QoL assessments



Safety: Intravenous MultiStem **well-tolerated** by ARDS patients, with no serious adverse reactions



ONE-BRIDGE: Healios study in Japan for the treatment of ARDS



MultiStem-treated
patients experienced:

Cohort 1 - Pneumonia-induced ARDS Patients	MultiStem	SOC
Number of Patients	20	10
Ventilator-free days (median)	20	11
Mortality (d90)	26%	43%

Cohort 2 - COVID-19 Induced ARDS Patients	MultiStem	SOC
Number of Patients	5	-
Ventilator-free days (median)	25	-
Mortality (d90)	0%	-

Note: Data disclosed by HEALIOS K.K.

SOC: Standard of Care



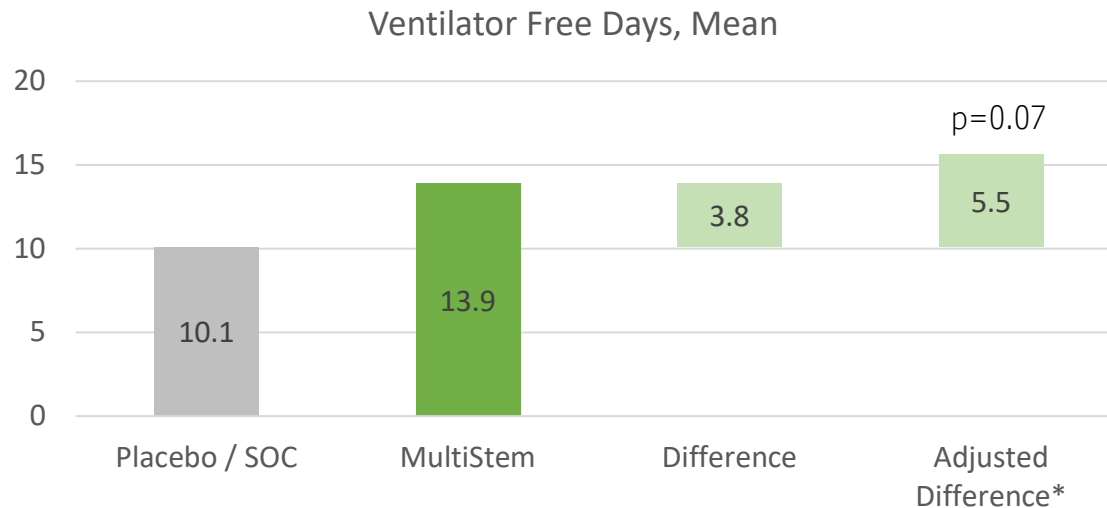
82% Increase in
Ventilator-free
days



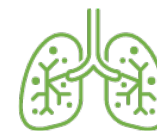
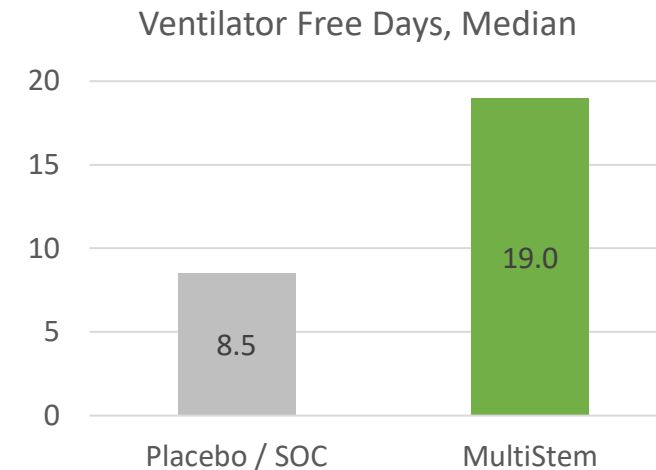
39% Reduction in
Mortality

Analysis of Pooled MUST-ARDS & ONE-BRIDGE Data – Results Signal MultiStem Treatment Potential

- 60 ARDS (non-COVID) patients – 40 receiving MultiStem treatment – 20 placebo or standard of care
- Mostly pneumonia-induced ARDS (85% MultiStem-treated subjects; 90% placebo / SOC subjects)
- MultiStem dose of 900 million cells delivered intravenously within 3 to 4 days of diagnosis



*Adjusted for differences in age and baseline pulmonary function



MultiStem treated had
a 124% Increase
in Ventilator-free days



Substantial Value Drivers for Treating ARDS with MultiStem



Based on MUST-ARDS clinical data, MultiStem-treated patients have **reduced number of days** in the ICU, which is the **most expensive** area of the hospital for healthcare costs



MultiStem-treated patients may be weaned off mechanical ventilators sooner, **saving healthcare costs** and improving chances of recovery



MultiStem treatment was associated with improved independence and Quality of Life for one-year ARDS survivors, which may **decrease the need** for medications, counseling, and other post-ARDS treatments.



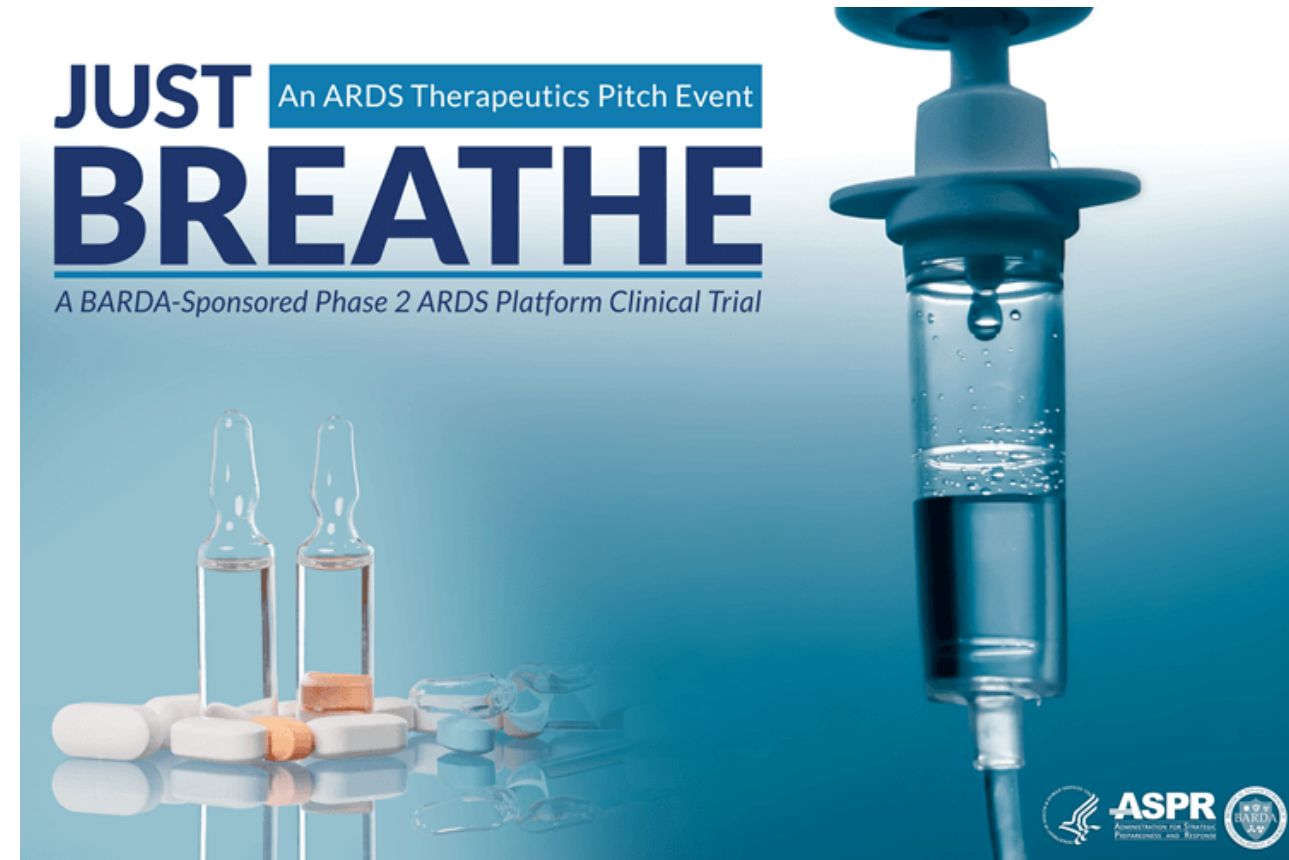
MultiStem represents a **high value intervention** which may **reduce direct costs** and **increase productivity** and **quality-adjusted life years** gained over the ARDS survivor's lifetime.



BARDA ARDS Phase 2 Trial Proposal

BARDA Proposal Process:

- **May 26, 2023** – Submitted pre-submission inquiries
- **June 30, 2023** – Submitted final (revised) slide deck and other submission materials
- **July 10, 2023** – Notified as finalist by BARDA
- **July 24-28, 2023** – Just Breathe – An ARDS Therapeutics Pitch Event
- **August, 2023** – Awardees notified



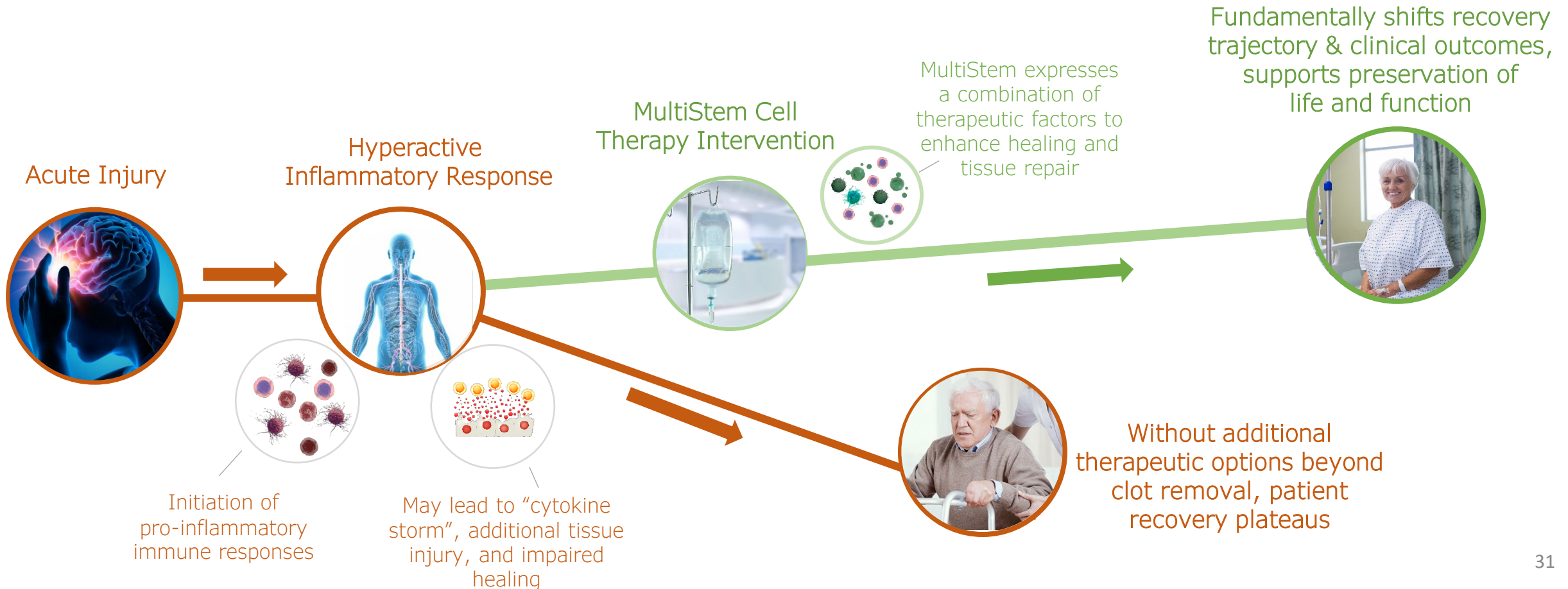


Mechanism of Action

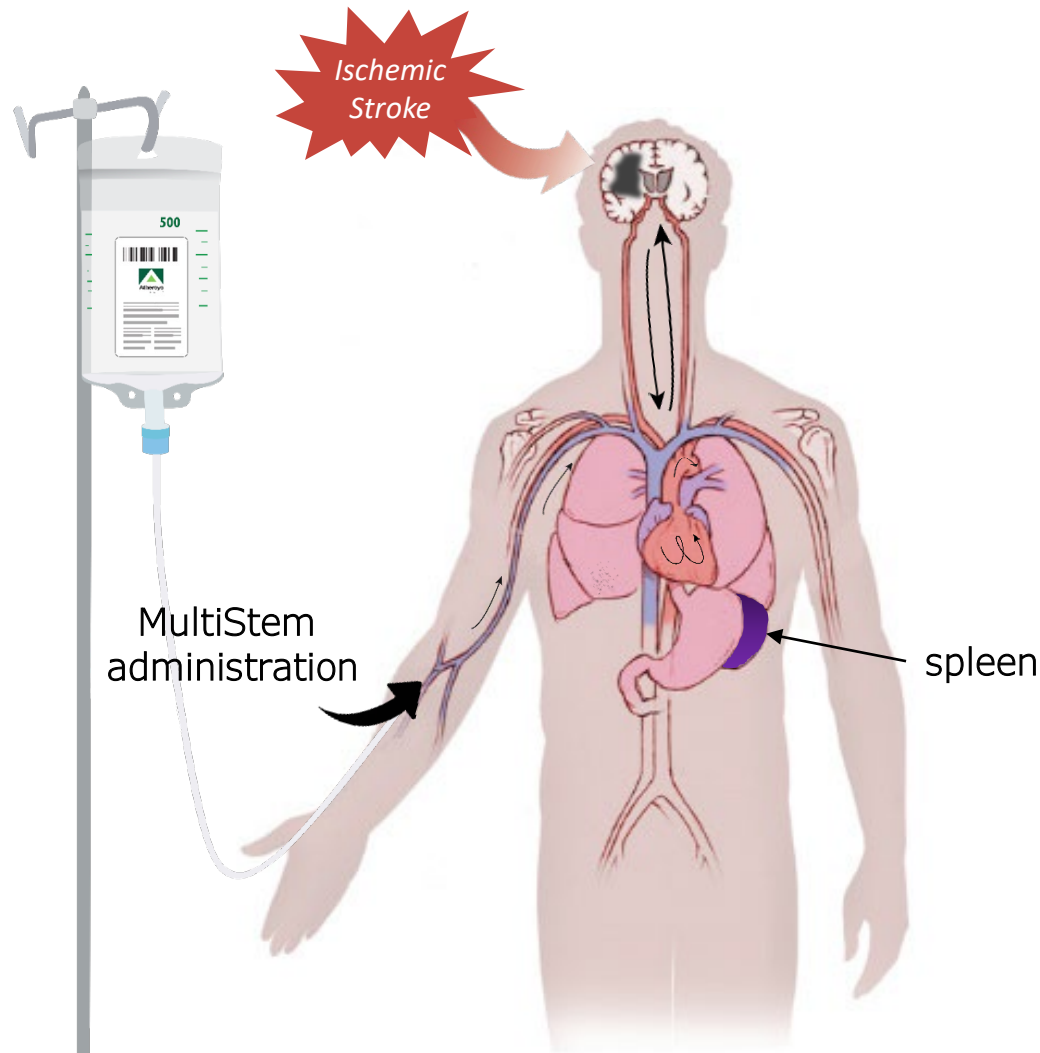
Overview of data from pre-clinical
and clinical understanding of
mechanism of action

MultiStem® Overview

Our data show that **early intervention** with MultiStem therapy after an acute injury enhances healing by regulating an overactive immune response and re-establishing homeostasis.



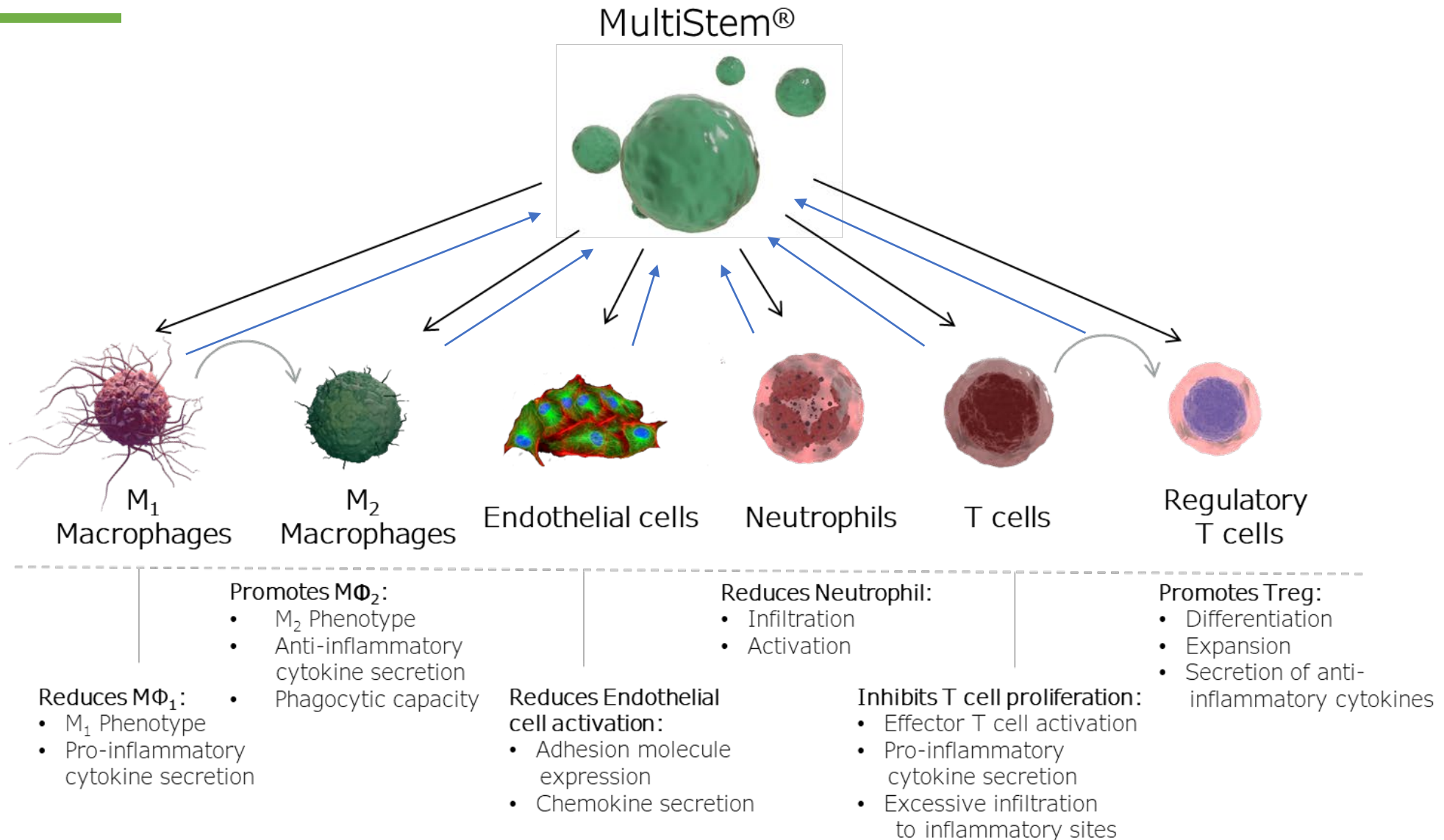
Key Events and Therapeutic Mechanism of Action of MultiStem following Ischemic Stroke



- 1 Ischemic stroke occurs when a blood clot blocks an artery leading to the brain, resulting in a corresponding loss of neurologic function.
- 2 Inflammation after stroke can lead to greater tissue loss and scarring in the brain and immune cells coming from the spleen play a major role this response.
- 3 MultiStem cells administered 18-36 hours post stroke migrate to the spleen, modulate splenic activation and peripheral immune responses.
- 4 The MultiStem-mediated decrease in pro-inflammatory signaling (ex, TNF, IL1 β , IL-6) and increase in reparative immune responses (ex, T regulatory cells) results in a more favorable environment in the brain for long term repair and restoration of function.

Representative Publication in *Stem Cells* (2017):
MAPCs Enhance Recovery After Stroke by Modulating
the Immune Response from the Spleen

Multimodal Mechanism of Action: A Living and Dynamic Product Capable of Interaction with Multiple Cell Types





Consistent Biomarker Impact Observed in Preclinical and Clinical Studies Reflect Mechanism of Action

MultiStem subjects compared to Placebo subjects Biomarker Levels at Day 7 relative to Baseline

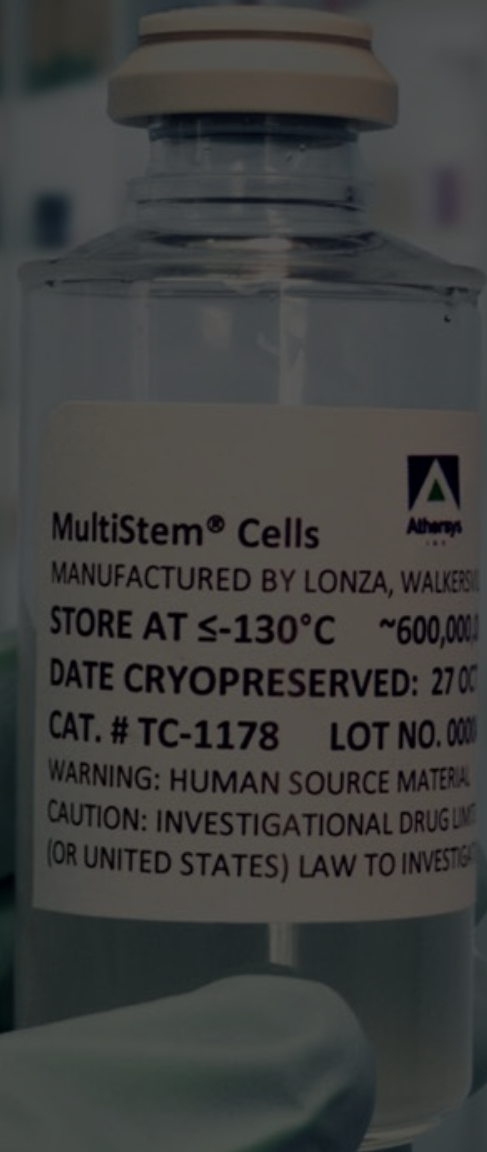
Cytokine	MUST-ARDS 20 MS, 10 P	MASTERS-1 (Ischemic Stroke) 65 MS, 61 P
IL-6	↓	↓↓
IL-12	↓↓	↓
IL-1b	↓↓	↓↓
IFNg	↓↓	↓↓
TNFa	↓	↓↓

Reduction in **acute inflammatory biomarkers** from MultiStem treatment observed in ARDS and Ischemic Stroke patients, consistent with previously published preclinical data

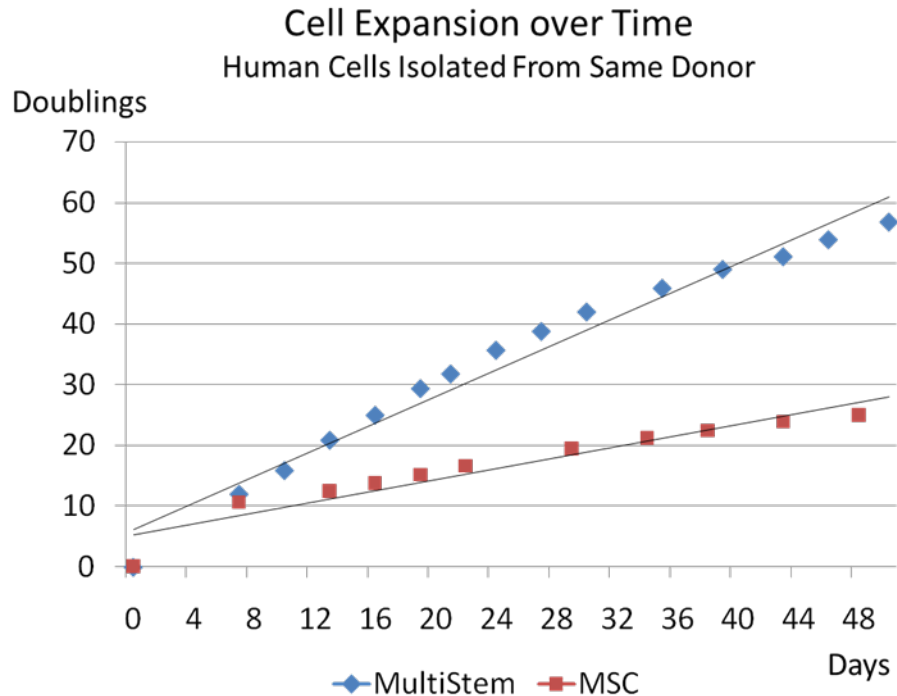


Manufacturing

Patented Platform Technology
Global Leader
Manufacturing Process



Expansion Capabilities of MultiStem



- MultiStem is cell therapy based on MAPC® technology that can **double rapidly in culture** and have **robust expansion capabilities**, beyond other bone marrow-derived cell therapies, as seen in the chart to the left comparing MultiStem to MSCs
- **Hundreds of thousands of doses** can be generated from one single donor
- Cells are expandable in bioreactors with **~10x greater output** which enables us to **scale production** with **significant reduction in cost per dose**
- **Demonstrated product stability** – long shelf life for MultiStem product, >5 years
- Extensive characterization of the product including two proprietary **potency assays**



Scalable Manufacturing Process

15 Years of Production Experience and Advancements in Cell Therapy:

- Proven expertise in efficient, high yielding and innovative processes
- Establishment of an essentially closed manufacturing process - unique characteristic in the Cell & Gene Therapy industry
- Advancement of a large-scale cell therapy manufacturing process at increasing scales to support commercial manufacturing – building upon expertise from Cell Factories to Bioreactors



T-Flask

- Used in Process Development Activities
- Pre 2007



2D

- 10 Layer Cell Factory
- Year 2007 to present
- ~ 6 Doses per Batch
- 150 Production Runs Completed

Most Cell Therapy
Companies are Here



3D 1.0

- 4 x 40 Liter Single Use Bioreactors
- Year 2017 to 2020
- 20 – 25 Doses per Batch
- 20+ Production Runs Completed



3D 2.0

- 1 x 200L FPI/1 x 500L DP Single Use BRs
- 2020 to present
- 75-100 Doses per 500 L Bioreactor
- 2 Development Runs Completed
- Xeno-free process



Thank you!
