
Pluristem
Therapeutics Inc.
COMPANY PRESENTATION
October 2017
INSPIRED by LIFE

Forward looking Statement

This presentation contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, we are using forward-looking statements when we discuss the expected timing of obtaining regulatory approval for our various patient trials and clinical data readout, proposed trials that may occur in the future, the timing and implementation of our collaborations with various partners and the execution of definitive agreements relating to such collaborations and the potential benefits and impact our products could have on improving patient health care. These forward-looking statements and their implications are based on the current expectations of our management only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause our actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, we undertake no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting us, reference is made to our reports filed from time to time with the Securities and Exchange Commission

CORPORATE OVERVIEW

- Cell therapy company using off the shelf placenta-derived cell products
- Entering late-stage trials in 3 indications
- Multifactorial therapy releasing a range of therapeutic proteins in response to signals from patient's body
- First in class 3D cell culturing technology allowing for efficient, controlled production of different cell products in commercial quantities

FINANCIAL GLANCE

Pluristem Therapeutics Inc.	NASDAQ: PSTI TASE: PSTI
Stock Price (As of 10/27/2017)	$1.97
Market Capitalization	~$192 million
Cash and Marketable Securities (As of 6/30/2017)	$26.7 million
Debt	$0
Employees	180
Intellectual Property Ownership	115+ granted ~100 pending

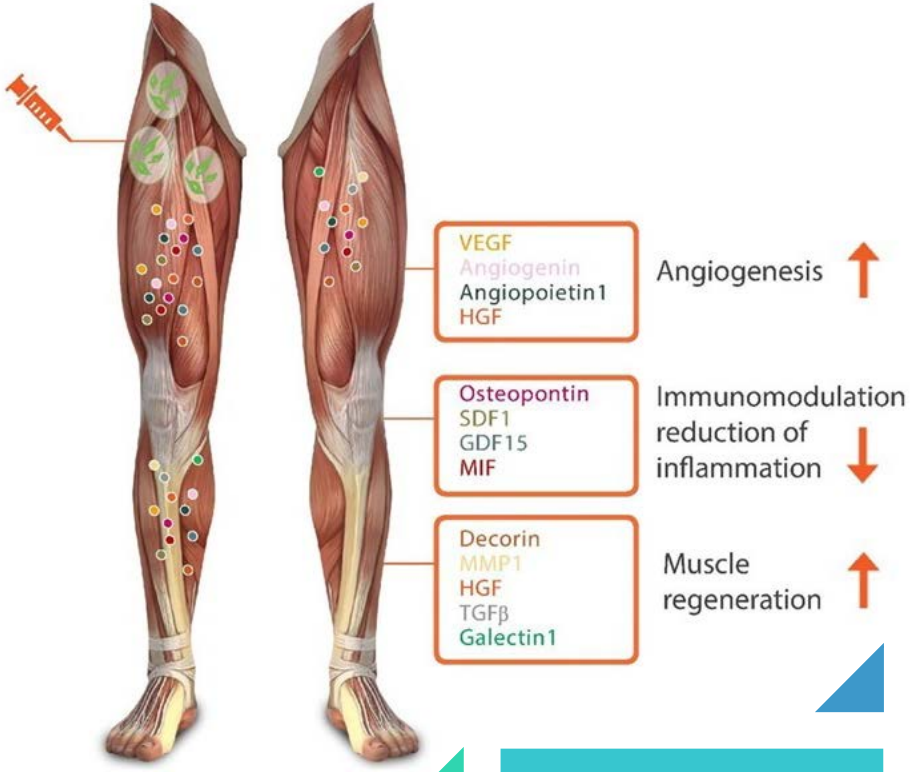
PLURISTEM in one slide

Placenta

Technology

Allogenic off-the-shelf

Simple IM administration



Adaptive slow release secretion of cytokines

long term regenerative effect

The PLX Platform Technology

Best In Class GMP Facility

3D Manufacturing, In-house Cell Production

Potential capability to manufacture up to 150,000 doses annually

Manufacturing CMC* approved by

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

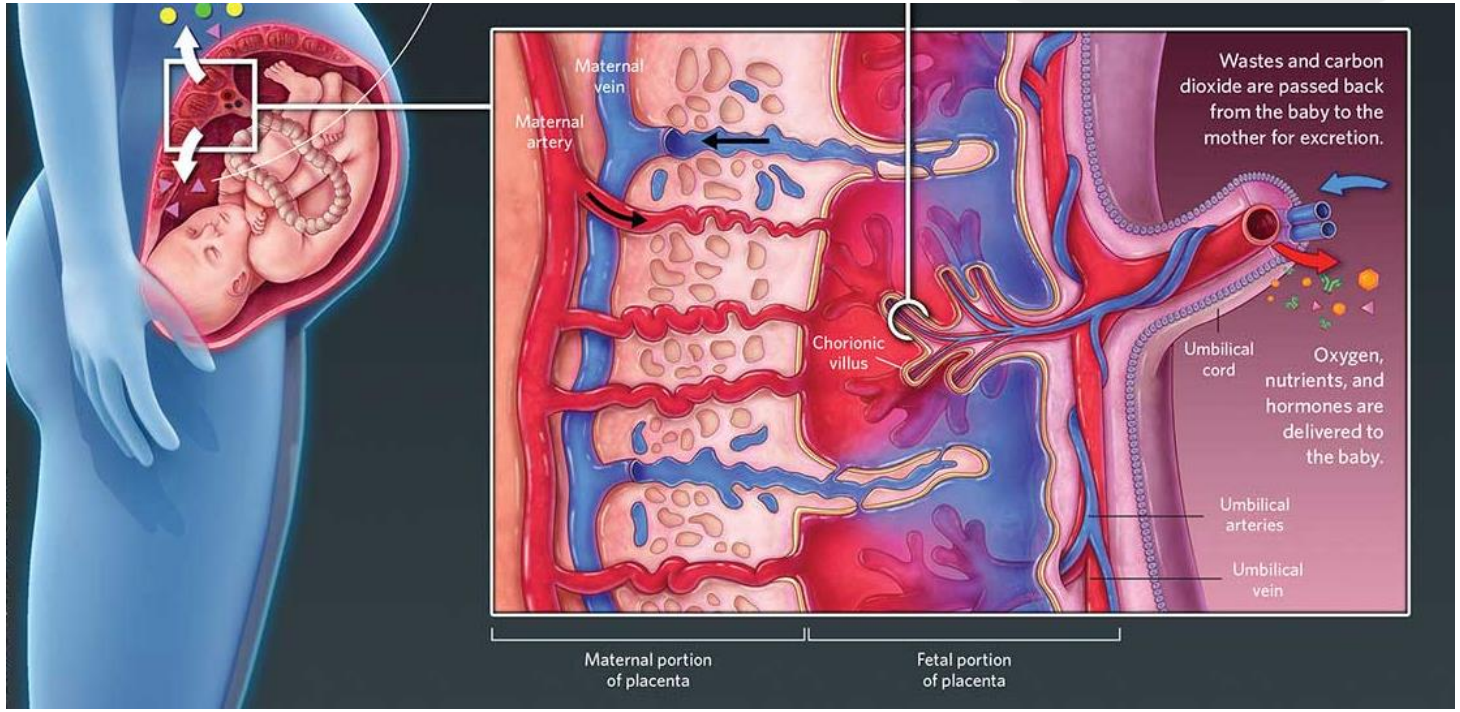
Pmda JAPAN

מדינת ישראל
משרד הבריאות
Ministry of Health Israel

* Chemistry, Manufacturing, and Controls

Placenta Derived Cells

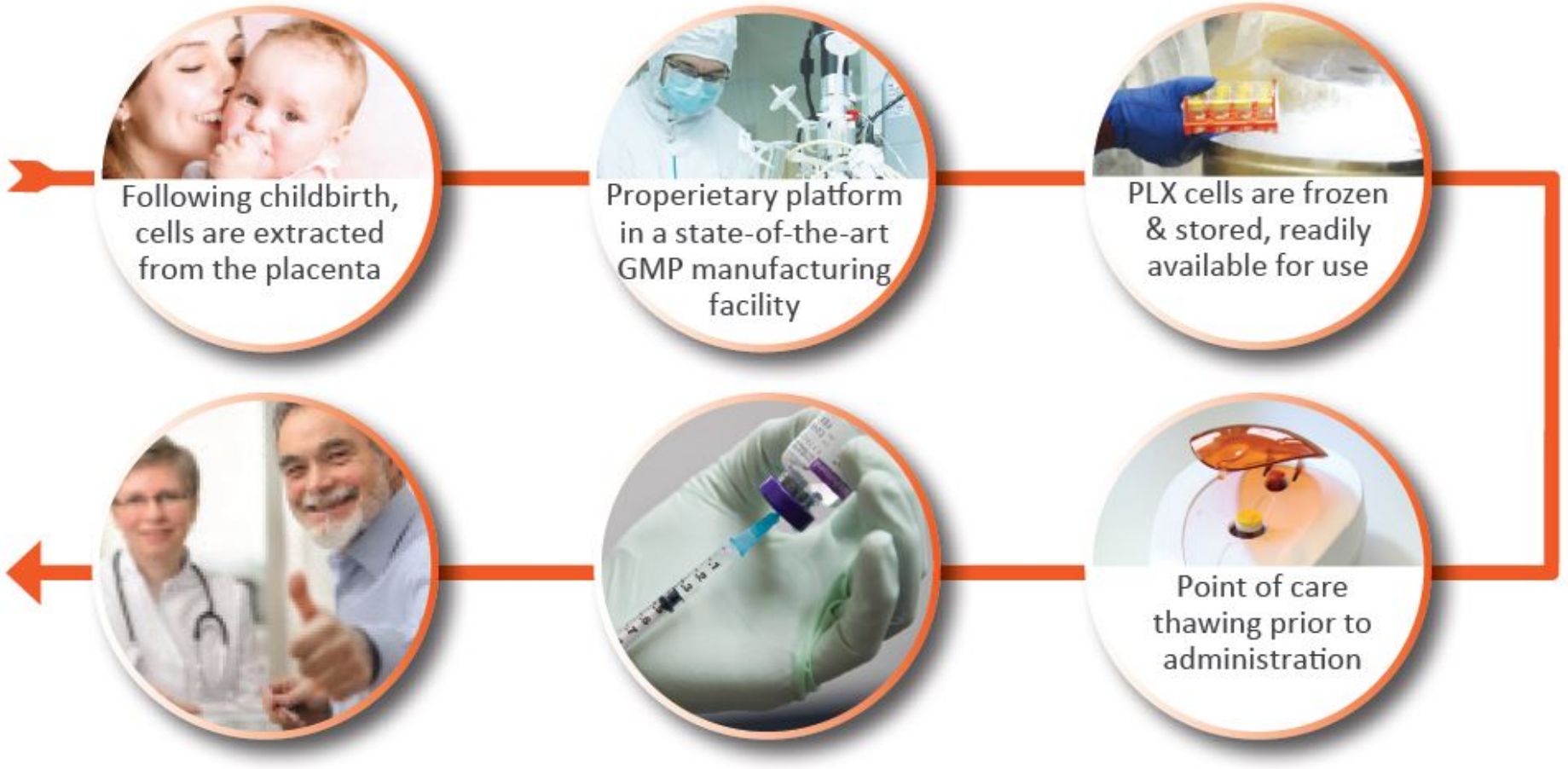
- Ethically accepted
- Rich & Diverse
- Highly potent
  - Pro-angiogenic
  - Immunoregulatory
- Young donors
- Unlimited source & Easy to collect
- Over 25,000 Doses of 300 million cells per placenta



http://www.the-scientist.com/?articles.view/articleNo/43618/title/The-Prescient-Placenta/

The Placenta Project was Launched by the US National Institutes of Health (NIH) to further explore the role of the placenta in health and disease

From The Miracle of Birth to Therapeutics for All



Company Pipeline

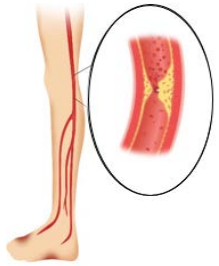
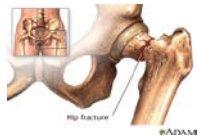
Late-stage trials

Indication	Product	Location	Pre-Clinical / Phase 1 / Phase 2 / Phase 3	Funding
Critical Limb Ischemia (CLI)	PLX-PAD	U.S. Europe*		
		Japan**	Single pivotal study 	
Intermittent Claudication (IC)	PLX-PAD	U.S., Europe S. Korea, Israel		
Hip Fracture* **	PLX-PAD	U.S. Europe		
Acute Radiation Syndrome (ARS)	PLX-R18	U.S.	Pivotal study via FDA Animal Rule 	

* One Multinational trial- U.S- phase 3, Europe- via adaptive pathway potentially allowing early marketing approval
** Via PMDA's accelerated regulatory pathway for regenerative therapies
*** Pending FDA/EMA approval

A CHANGE IN REGULATORY ENVIRONMENT

Regulatory Status

	FDA	EMA	PMDA
CLI (PLX-PAD) 	• Fast track approval • Single pivotal study (n=246)	• Adaptive regulatory pathway • Single pivotal study (n=246) • Potential conditional approval on interim report (n=123)	• Accelerated regulatory pathway • Single pivotal study (n=75)
Hip fracture (PLX-PAD) 	• Pivotal study • Subject to FDA approval	• Adaptive regulatory pathway • Single pivotal study	
ARS (PLX-R18) 	• Animal rule pathway • Open communication, unlimited pre- IND		

PLX-PAD

- Reduces inflammation
- Stimulates growth of collateral blood vessels
- Stimulates repair of damaged muscle

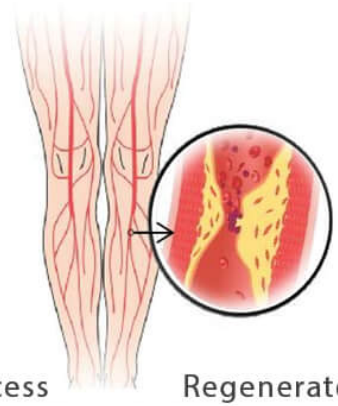
Peripheral Arterial Diseases

Orthopedic Injuries

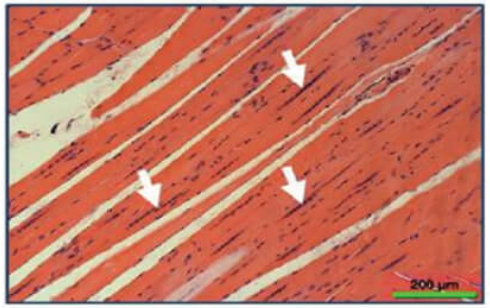
PLX-PAD Mechanism of Action

Ischemia

Inflammation | Loss of muscle tissue

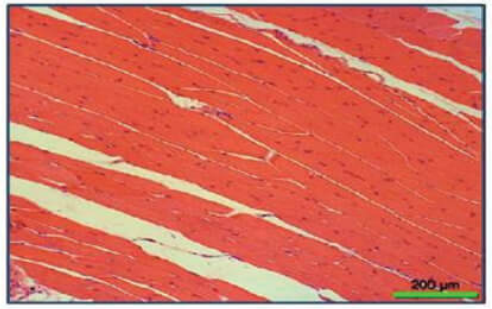


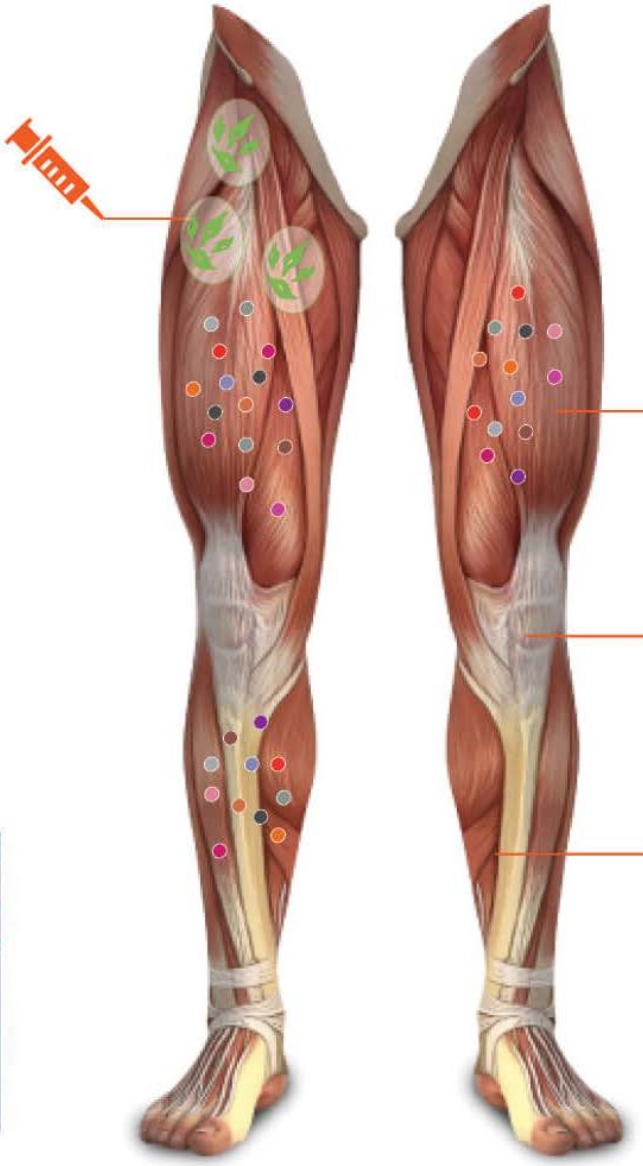
Muscle Recovery in process



Rows of myoblast nuclei indication regenerative hyperplasia

Regenerated muscle tissue





- VEGF
- Angiogenin
- Angiopoietin1
- HGF

Angiogenesis ↑

- Osteopontin
- SDF1
- GDF15
- MIF

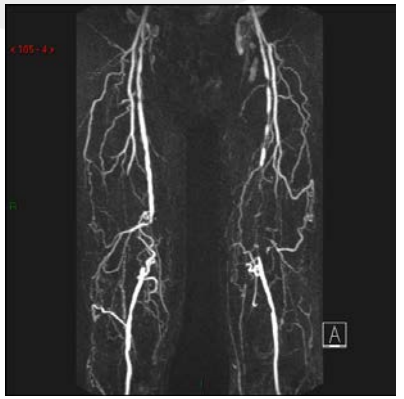
Immunomodulation: reduction of inflammation ↓

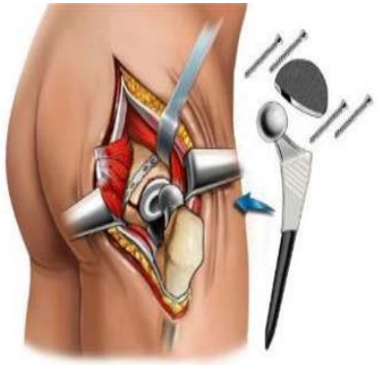
- Decorin
- MMP1
- HGF
- TGFβ
- Galectin1

Muscle regeneration ↑

Completed and Ongoing Clinical Studies with PLX-PAD

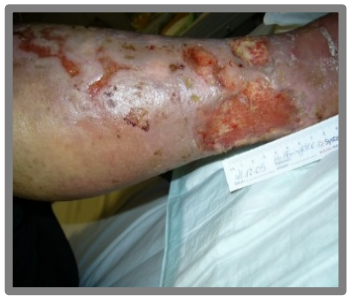
- **Two <u>completed</u> Phase I studies in Critical limb ischemia (CLI) in U.S. and Germany, N=27**
  - ✓ Good safety profile
  - ✓ Trends of efficacy (pain reduction and increase in tissue perfusion)
- **<u>Ongoing</u> multinational Phase II study in Intermittent claudication (IC) in U.S., Germany, South Korea and Israel, N=172**
  - ✓ Enrollment completed
  - ✓ Data readouts expected in H1 2018
- **<u>Completed</u> Phase II study in muscle injury following total hip replacement in Germany, N=20**
  - ✓ Good safety profile
  - ✓ Strong efficacy (increase in muscle volume and muscle force)



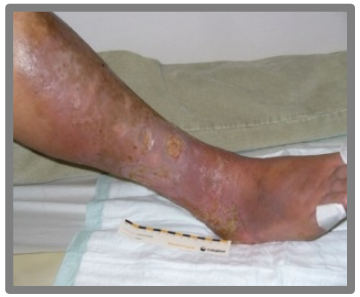


Completed and Ongoing Clinical Studies with PLX-PAD

- **<u>Ongoing</u> multinational Phase III study In Critical Limb Ischemia (CLI) in U.S., Europe, N=246**
  - ✓ Fast track designation from FDA
  - ✓ Adaptive regulatory pathway from EMA
  - ✓ Support from EU Horizon 2020 program
- **<u>Planned</u> multinational Phase III study In Hip Fracture in U.S., Europe**
  - ✓ Adaptive regulatory pathway from EMA
  - ✓ Support from EU Horizon 2020 program
- **<u>Planned</u> Pivotal study in CLI in Japan, N=75**
  - ✓ PMDA's accelerated regulatory pathway for regenerative therapies
  - ✓ Form joint venture



Pre-Treatment



8 Weeks post treatment

Company Pipeline

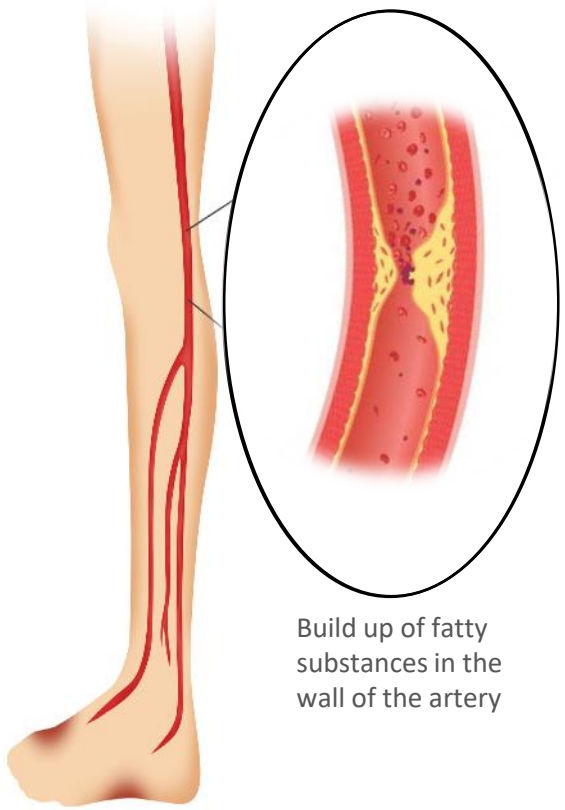
Late-stage trials

Indication	Product	Location	Pre-Clinical / Phase 1 / Phase 2 / Phase 3	Funding
Critical Limb Ischemia (CLI)	PLX-PAD	U.S. Europe*		
		Japan**	Single pivotal study 	
Intermittent Claudication (IC)	PLX-PAD	U.S., Europe S. Korea, Israel		
Hip Fracture* **	PLX-PAD	U.S. Europe		
Acute Radiation Syndrome (ARS)	PLX-R18	U.S.	Pivotal study via FDA Animal Rule 	

* One Multinational trial- U.S- phase 3, Europe- via adaptive pathway potentially allowing early marketing approval
** Via PMDA's accelerated regulatory pathway for regenerative therapies
*** Pending FDA/EMA approval

Peripheral Arterial Disease (PAD)

- PAD is caused by fatty deposits in leg arteries that obstruct blood flow
- Intermittent claudication is the early stage while critical limb ischemia (CLI) is the more advanced stage of PAD
- CLI Patients suffer from severe pain at rest, skin wounds, tissue necrosis and poor quality of life with a **high risk of leg amputation and death**
- 5-6 million people in U.S. and Europe suffer from CLI*
- Estimated cost for treatment in the U.S. is over $25 billion per year*
- Up to 40% of patients are unsuitable for revascularization and experience up to a 40% amputation rate at 1 year**



Build up of fatty substances in the wall of the artery

*Source: Sage Group- (link, link, link)
**Source: European Society for Vascular Surgery (link)

CLI Phase III Study -U.S./ Europe (N=246)

- Accelerated regulatory pathways in U.S. (Fast Track), Europe (Adaptive regulatory pathway) & Japan (accelerated regulatory pathway for regenerative therapies)
- **An interim analysis (N=123) of efficacy will be performed in support of an application to the EMA for Conditional Marketing Authorization (CMA)**
- Interim analysis could lead to CMA based on the success of either the primary or one of the key secondary endpoints, or a composite endpoint that includes death, major amputation, and certain measures of severity of wounds and gangrene
- Primary endpoint is time to event (amputation or death); other measures of efficacy include AFS, quality of life, $TcPO_2$, and pain score
- Dosing regimen: two doses of 300 million cells, two months apart (n=144), placebo (n=72)
- No HLA matching or immunosuppression required
- Follow-up of 12-36 months increases the study's power allowing for a smaller trial

$8 million grant from the EU Horizon 2020 program to support Phase III trial

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Clinical Development of CLI in Japan

- Accepted to the PMDA's accelerated regulatory pathway for regenerative therapies
- A single 75 patient study may lead to early conditional marketing approval and reimbursement
- Binding term sheet with Sosei CVC to establish joint venture for the clinical development and commercialization of PLX-PAD for CLI in Japan

Company Pipeline

Late-stage trials

Indication	Product	Location	Pre-Clinical / Phase 1 / Phase 2 / Phase 3	Funding
Critical Limb Ischemia (CLI)	PLX-PAD	U.S. Europe*		
		Japan**	Single pivotal study 	
Intermittent Claudication (IC)	PLX-PAD	U.S., Europe S. Korea, Israel		
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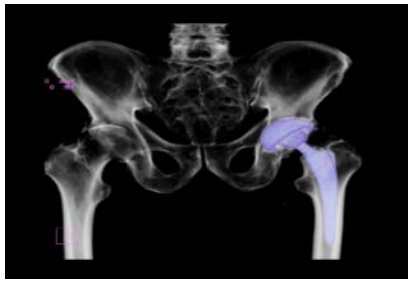
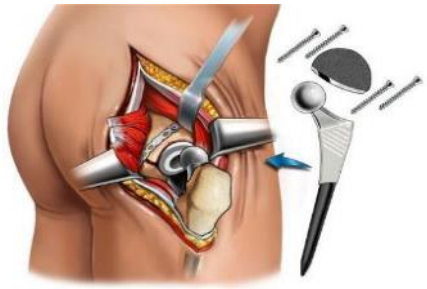
Muscle Regeneration- clinical data

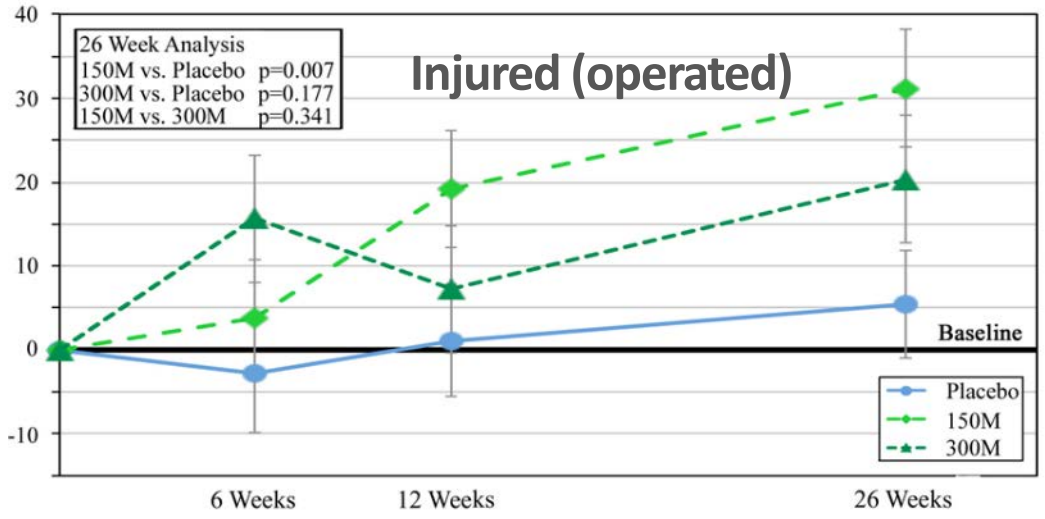
Muscle injury following total hip replacement (N=20)

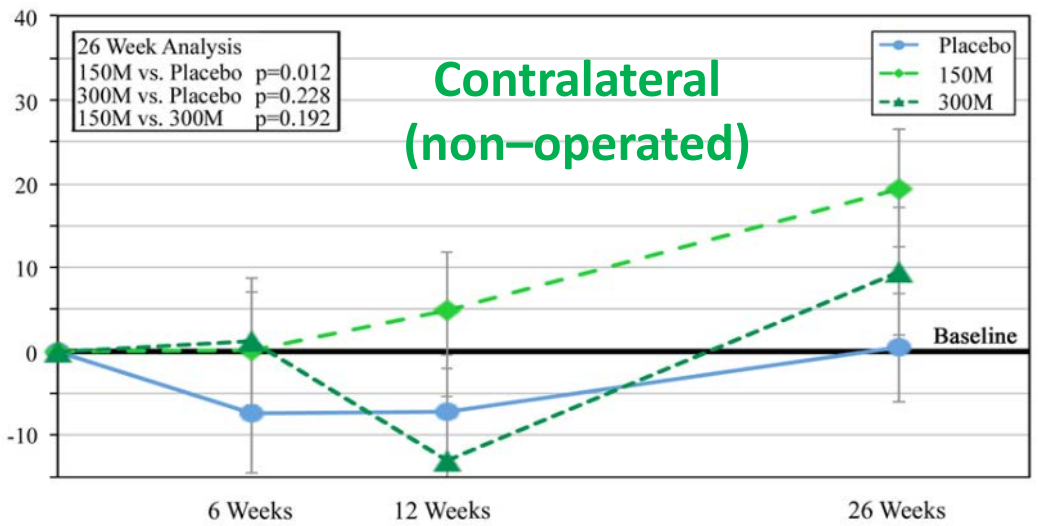
Improvement of 500% P=0.0067





Improvement of 4000% P=0.012



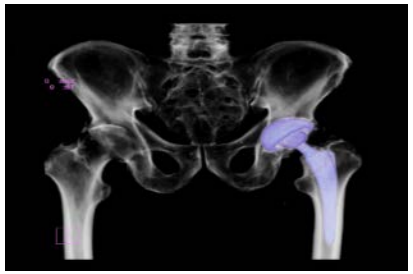


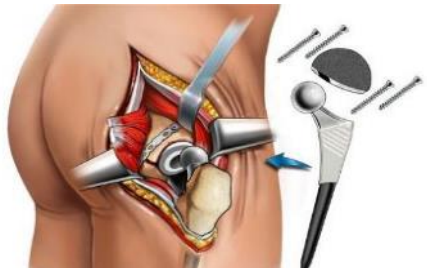
CHARITÉ

Pluristem Therapeutics Inc.

Muscle Regeneration- clinical data

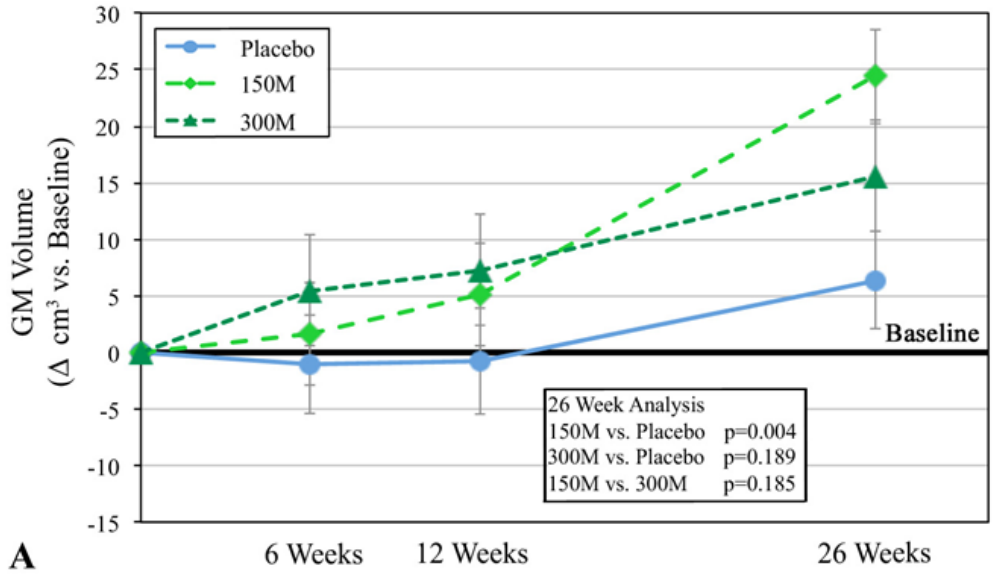
Muscle Injury following Total Hip Replacement (N=20)

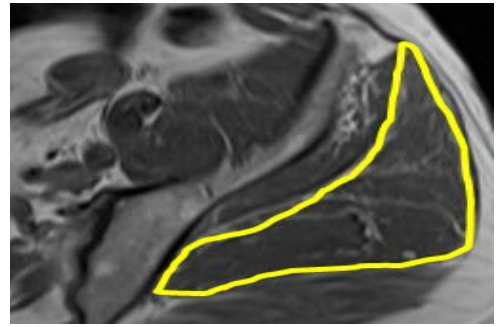


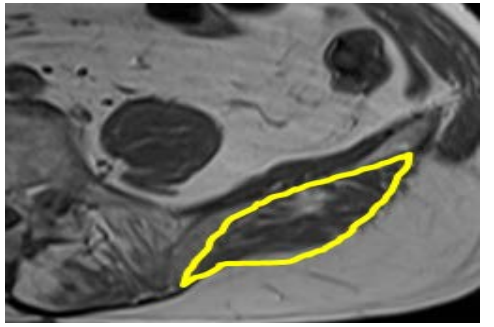


Change in Volume from Day 0

Improvement of 300% P=0.004







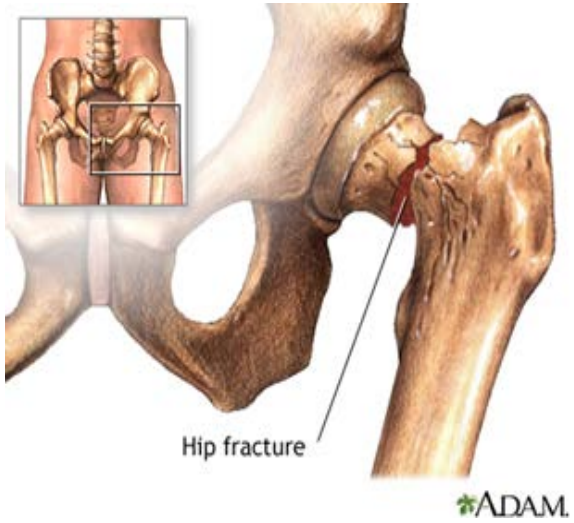
BERLIN CENTER FOR REGENERATIVE THERAPIES

CHARITÉ

Pluristem Therapeutics Inc.

Phase III Hip Fracture Study

- Femoral neck fracture is the most common form of hip fracture
- Annual treatment costs in the U.S. are estimated to be between $10 to $15 billion, and are expected to rise due to the aging population, with mortality rates of up to 36%*
- Positive feedback from FDA and EMA on the proposed study design and endpoints of Phase III trial in treatment for muscle recovery following arthroplasty for hip fracture
- PLX-PAD program in hip fracture might be eligible for Breakthrough Therapy designation and benefit from the 21st Century Cures Act as well as the EMA's Adaptive Pathways pilot project



$8.7 million grant from the EU Horizon 2020 program to support this Phase III trial

* Source: Simran Mundi, Bharadwaj Pindiprolu, Nicole Simunovic, Mohit Bhandari

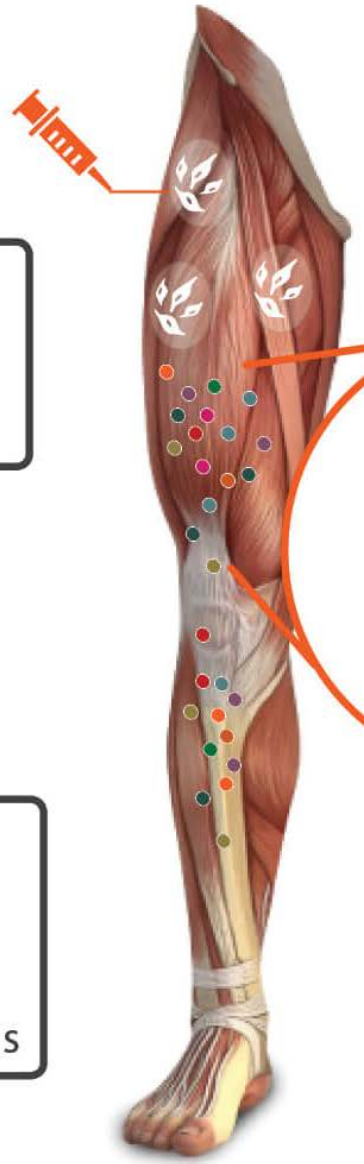
PLX-R18

- Stimulates regeneration of damaged bone marrow to produce blood cells (white, red and platelets)

Acute Radiation Syndrome (ARS)

Hematologic Indications

PLX-R18 Mechanism of Action



Chemotherapy, Drugs side effect, BM malignant infiltration, AA , BMT failure

Acute Radiation Syndrome (ARS)

Bone Marrow Failure

Low red blood cell count → severe anemia

Low white blood cell count → infections

Low platelet count → internal and external bleedings

- Epo
- SCF
- IL3

Red blood cells

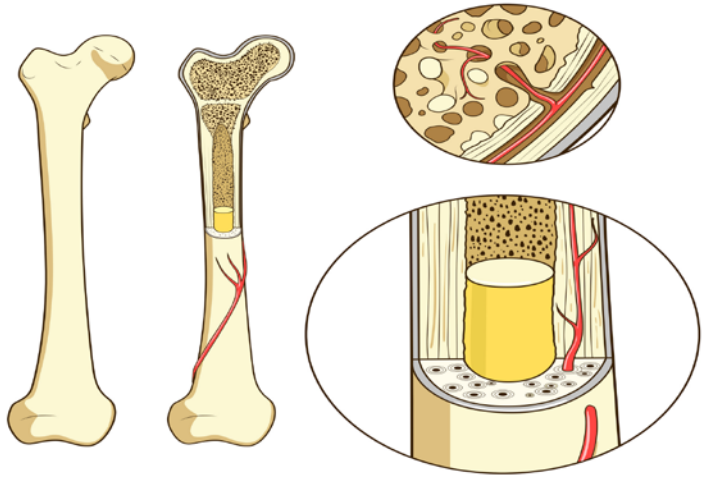
- G-CSF
- GM-CSF
- IL6
- IL8
- MCP1
- IL3
- HGF

White blood cells

- IL3
- SCF
- IL6

Platelets

PLX-R18 Programs



Acute Radiation Syndrome (ARS)

In Preparations for pivotal study

Bone Marrow Failure

Following or in support of a transplant of hematopoietic stem cells (HCT)

Ongoing Phase I study in U.S and Israel

Hematological Disorders

Autoimmune diseases, Genetic disorders, Chemotherapy, Radiation therapy, Side effects from treatments

Covered by patent

Company Pipeline

Late-stage trials

Indication	Product	Location	Pre-Clinical / Phase 1 / Phase 2 / Phase 3	Funding
Critical Limb Ischemia (CLI)	PLX-PAD	U.S. Europe*		
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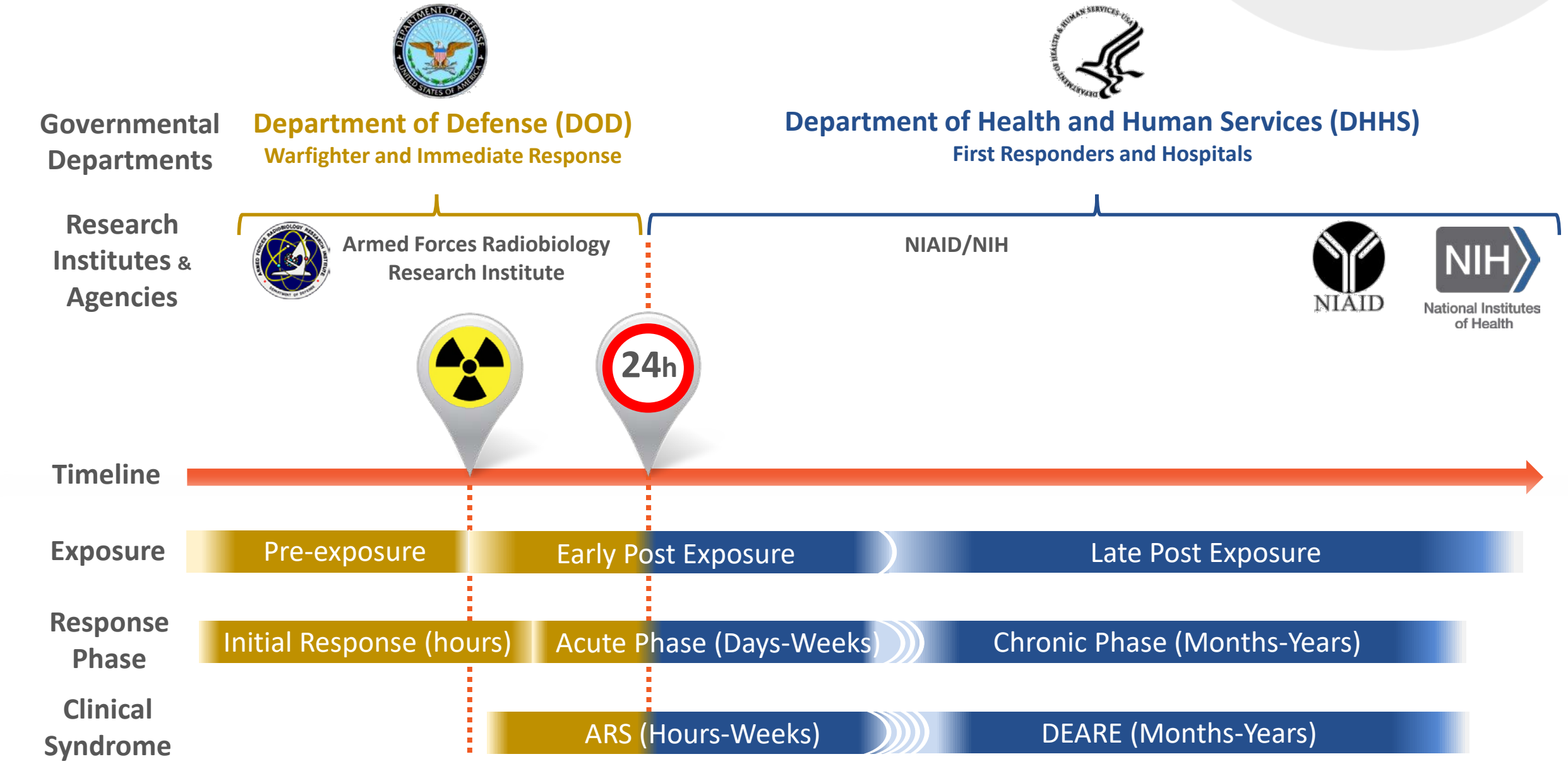
Acute Radiation Syndrome
ARS

ARS occurs following acute exposure to very high levels of radiation, and involves severe, potentially lethal injury to the bone marrow as well as to other organs and systems within the body

High doses of radiation can destroy the bone marrow's ability to produce white cells, red cells and platelets; without these cells patients are at high risk of death

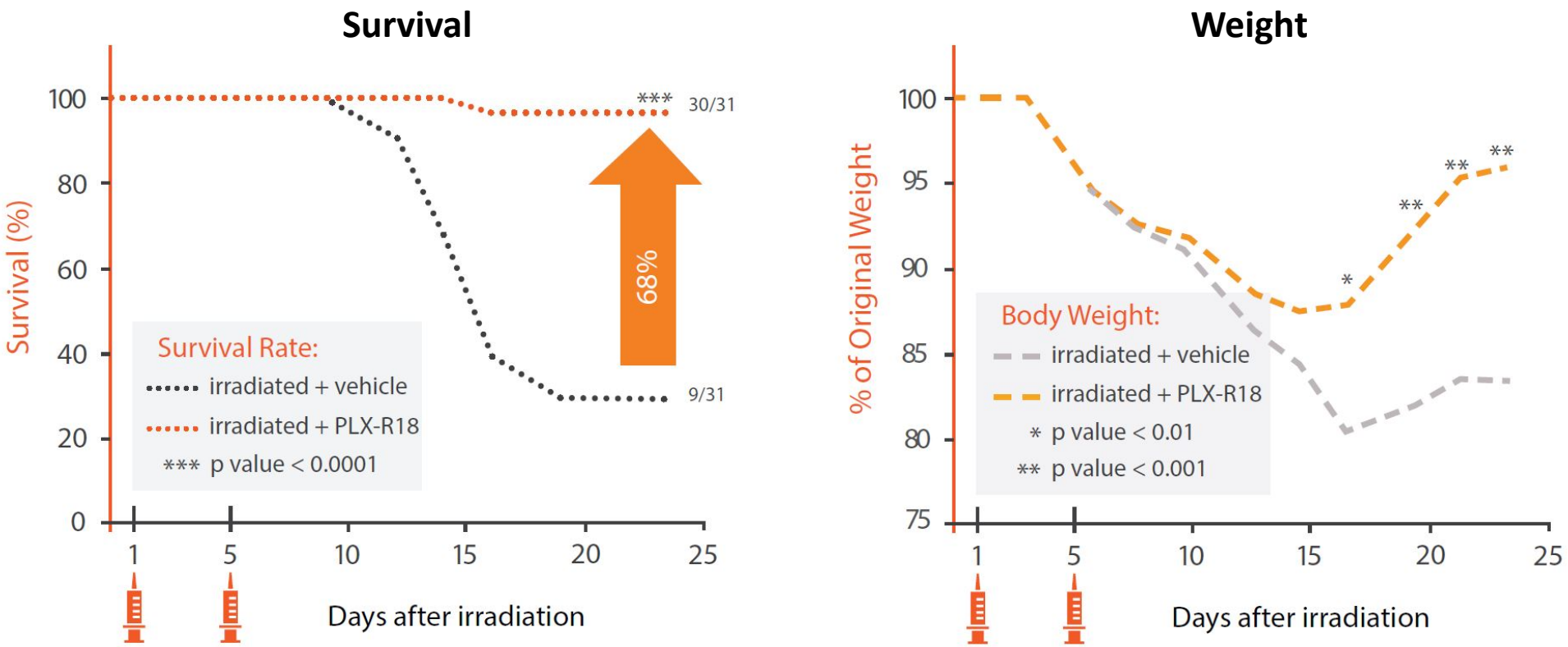
Collaboration on ARS with U.S. Government



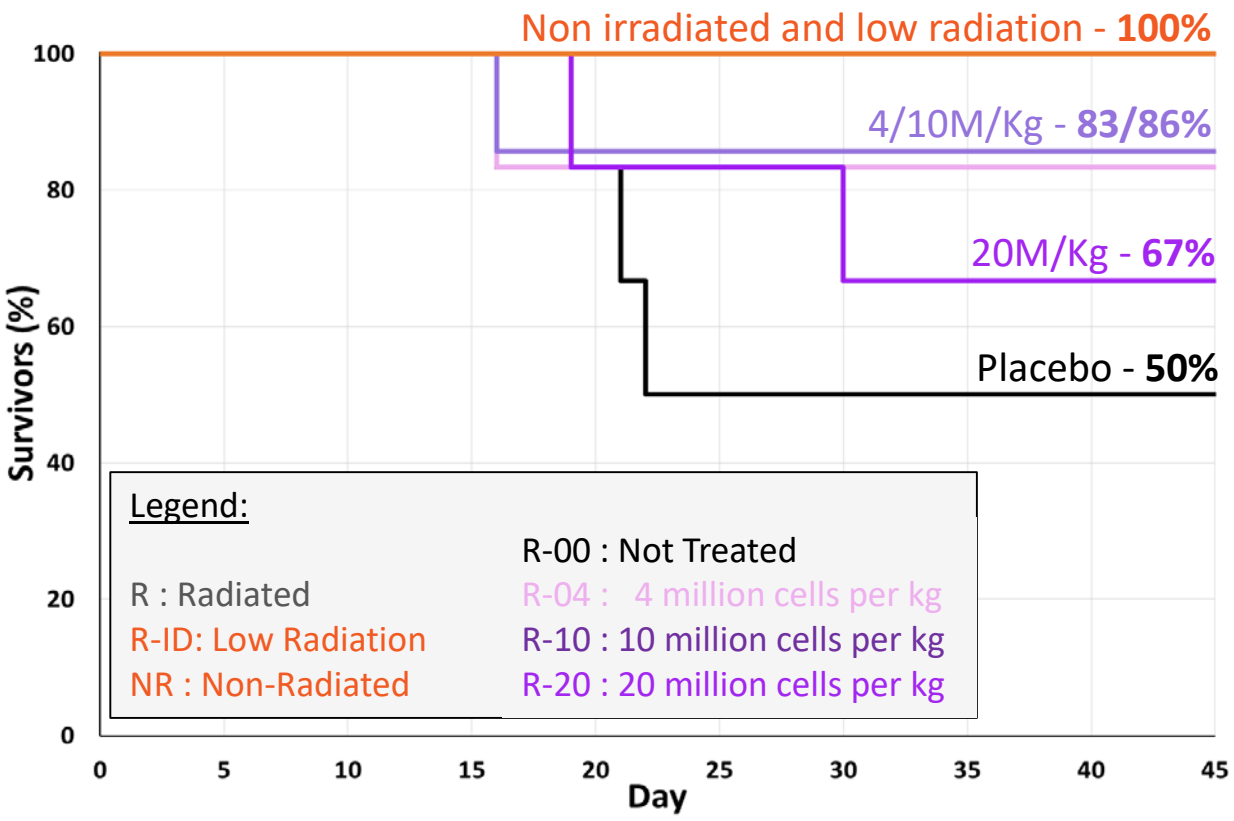
Collaboration on ARS with U.S. Government

Studies are conducted and funded by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) and U.S the department of defense

PLX-R18 Data- Phase I equivalent study (FDA animal rule)



PLX-R18 Data- Phase II equivalent study (N=62) (FDA animal rule)



Group	Females	Males	Females and Males	Total	04+10 only
NR-00	3/3 = 100%	3/3 = 100%	6/6 = 100%	6/6 = 100%	
NR-04	3/3 = 100%	3/3 = 100%	6/6 = 100%	18/18 = 100%	
NR-10	3/3 = 100%	3/3 = 100%	6/6 = 100%		
NR-20	3/3 = 100%	3/3 = 100%	6/6 = 100%		
R-00	1/3 = 33%	2/3 = 67%	3/6 = 50%	3/6 = 50%	
R-04	2/3 = 67%	3/3 = 100%	5/6 = 83%	15/19 = 79%	11/13 = 85%
R-10	3/4 = 75%	3/3 = 100%	6/7 = 86%		
R-20	2/3 = 67%	2/3 = 67%	4/6 = 67%		
R-Id-00	-	3/3 = 100%		3/3 = 100%	
R-Id-04		3/3 = 100%			
R-Id-10		3/3 = 100%			
R-Id-20		3/3 = 100%			

PLX-R18- Treatment of ARS

- ✓ Allogeneic, ready to use as an off the shelf product
- ✓ Easy IM administration
- ✓ Beneficial when administered even 48 hrs. following exposure to radiation
- ✓ No need for prescreening – no effect if injected to those who were not exposed to radiation
- ✓ Supports recovery of all three blood lineages (red and white cells and platelets)
- ✓ Long shelf life
- ✓ Showed increased survival rates In irradiated non-human primates (NHPs)

PLX-R18 Hematological Program

- ✓ Ongoing U.S. and Israeli Phase I clinical trial of R18 for the treatment of **insufficient hematopoietic recovery following hematopoietic cell transplantation**
  - N= up to 30
  - Open-label trial allows for interim data analysis
- ✓ Collaboration with the New York Blood Center to evaluate PLX-R18 as an **adjuvant therapy to umbilical cord blood transplantation in animal studies**
  - Grant of $900,000 from Israel-U.S. Binational Industrial Research and Development Foundation (BIRD)
- ✓ Granted European patent to cover indications related to the bone marrow's inability to produce blood cells, such as autoimmune diseases, genetic disorders, chemotherapy, radiation therapy, and side effects from other treatments

Commercialization Strategy

1. **Out-licensing** commercialization deals with partners

2. **Direct sales** of indications with small patients population & high market price

3. **Direct sales** of our PLX-R18 product for Acute Radiation Syndrome (governments)

Collaborations

Pluristem keeps IP and manufacturing rights in all collaborations

Partner	Indication	Deal structure
CHA Biotech	**IC, CLI** South Korea only	Joint Venture following marketing authorization by the South Korean authorities
NIH National Institute of Allergy and Infectious Diseases	**Acute Radiation Syndrome**	U.S. National Institutes of Health (NIH) to examine the effectiveness of PLX-R18 as a treatment for ARS following 24 hours from exposure
Department of Defense; Armed Forces Radiobiology Research Institute	**Acute Radiation Syndrome**	U.S. Department of Defense to examine the effectiveness of PLX-R18 prior to, and within the first 24 hours of exposure to radiation
Fukushima Medical University	**Acute Radiation Syndrome**	Pluristem will contribute cells and scientific knowledge, FMU will conduct the studies and provide the required resources.
Hadassah Medical Center	**Acute Radiation Syndrome**	Conducting trials to test PLX-R18 cells in the treatment of ARS and understanding of MOA
Charité	**CLI, Immunology, Cardiovascular, Orthopedic**	Research to test the unique immunology of the placenta and cells MOA
New York Blood Center	**Umbilical Cord Blood Transplantation**	Evaluating PLX-R18 as an Adjuvant Therapy to Umbilical Cord Blood Transplantation

Investment Highlights

INSPIRED by LIFE

- Publicly traded on the Nasdaq and Tel Aviv Stock Exchange [PSTI]
- Late-stage pipeline with products advancing towards commercialization and 3rd parties funding
- Advanced regulatory pathways that could shorten time to commercialization
- Expected near-term data readouts
- “Off the shelf” product, no HLA-matching required
- Unique multifactorial MoA with a vast scientific background
- Major technological competitive advantages
- Strong collaborations and partnerships

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Upcoming Milestones – 12 Months

- **Initiate pivotal trials**
  - ✓ Critical limb ischemia (CLI) – U.S., Europe (Japan yet to start)
  - Hip fracture – U.S., Europe
  - ARS
- **Clinical data readout**
  - Phase II Intermittent Claudication (IC)
  - Phase I incomplete engraftment of hematopoietic cell transplantation – open label
  - Pivotal study in ARS
- **Business development**
  - U.S. – Advance discussions with U.S. government regarding stockpiling of PLX-R18 for ARS
  - Japan- Finalize joint venture
  - Asia – Licensing/ joint venture with partner for Asian market

Management team

Zami Aberman
Chairman & Co-CEO

Efrat Livne-Hadass
VP Human Resources

Erez Egozi
CFO

Sagi Moran
VP Operations

Racheli Ofir, Ph.D.
VP Research & Intellectual Property

Yaky Yanay
President & Co-CEO

Esther Lukasiewicz Hagai, M.D., Ph.D.
VP Clinical & Medical Affairs

Orly Amiran
VP Quality Assurance

Lior Raviv
VP Development

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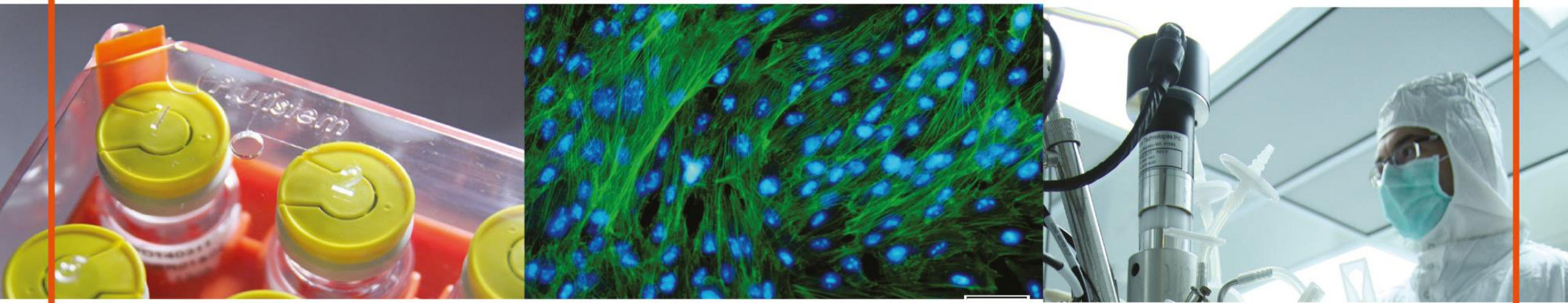

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