



# Clinical-grade solution for storage, transportation and administration of cell-based advanced therapy medicinal products (ATMP)

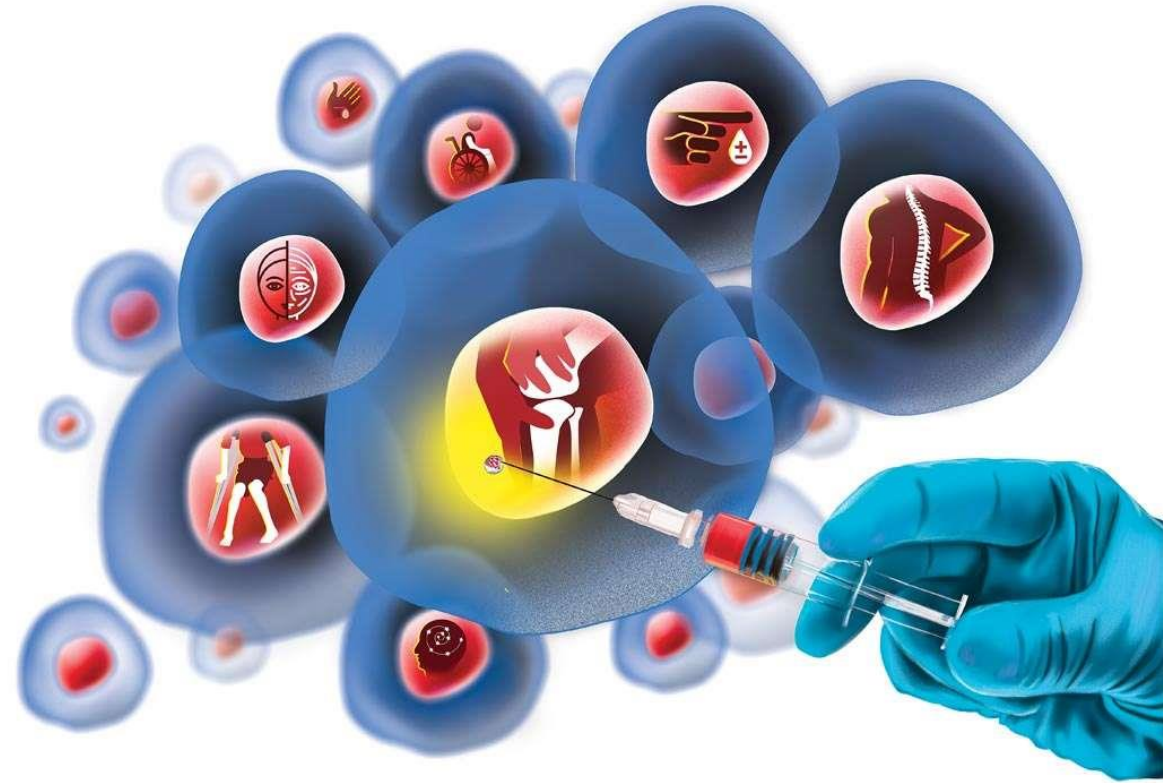
**Yuriy Petrenko, PhD**

Institute of Experimental Medicine CAS & Bioinova, s.r.o.



## Cell therapy at glance

Cell therapies deliver stem, primary or genetically modified cells, to facilitate regeneration of damaged cells within an organ/tissue



# Mesenchymal stem cells are currently the most applied cells type

## Mesenchymal Stem cells Properties

### REGENERATIVE

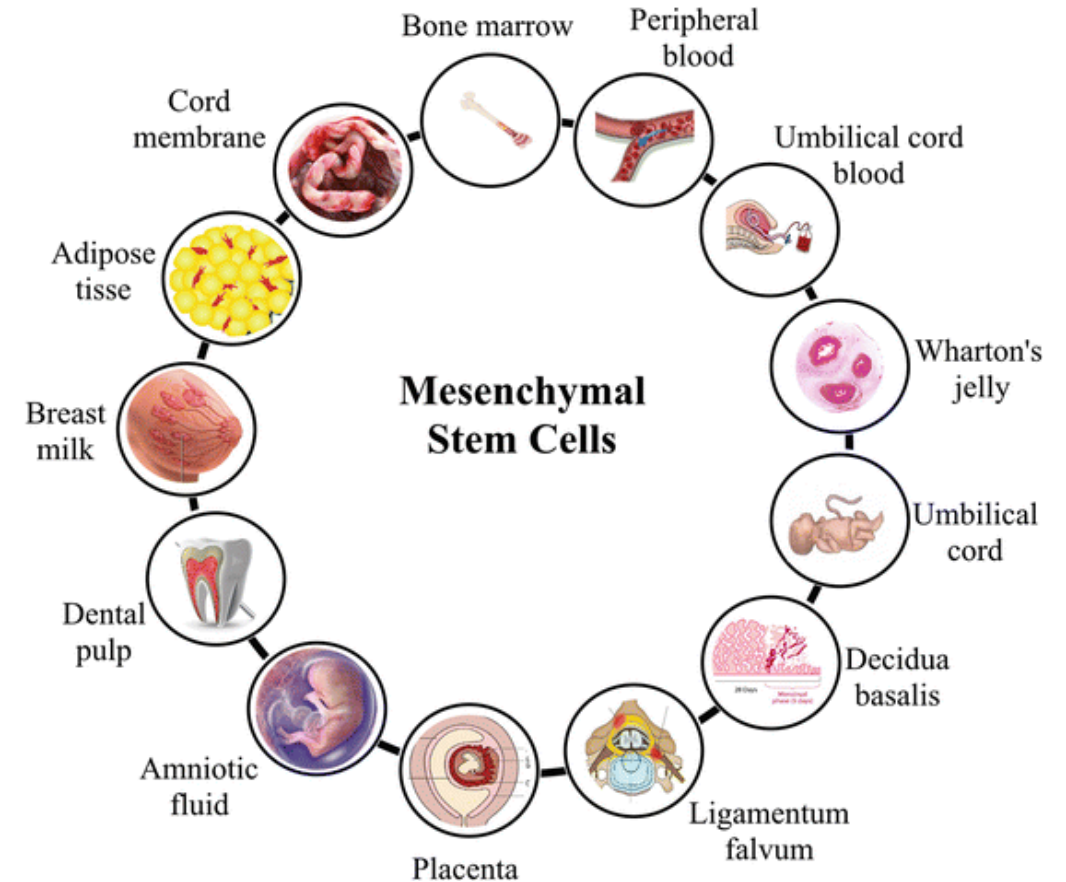
They seek out degeneration, build, repair and grow new tissues

### ANTI-INFLAMMATORY

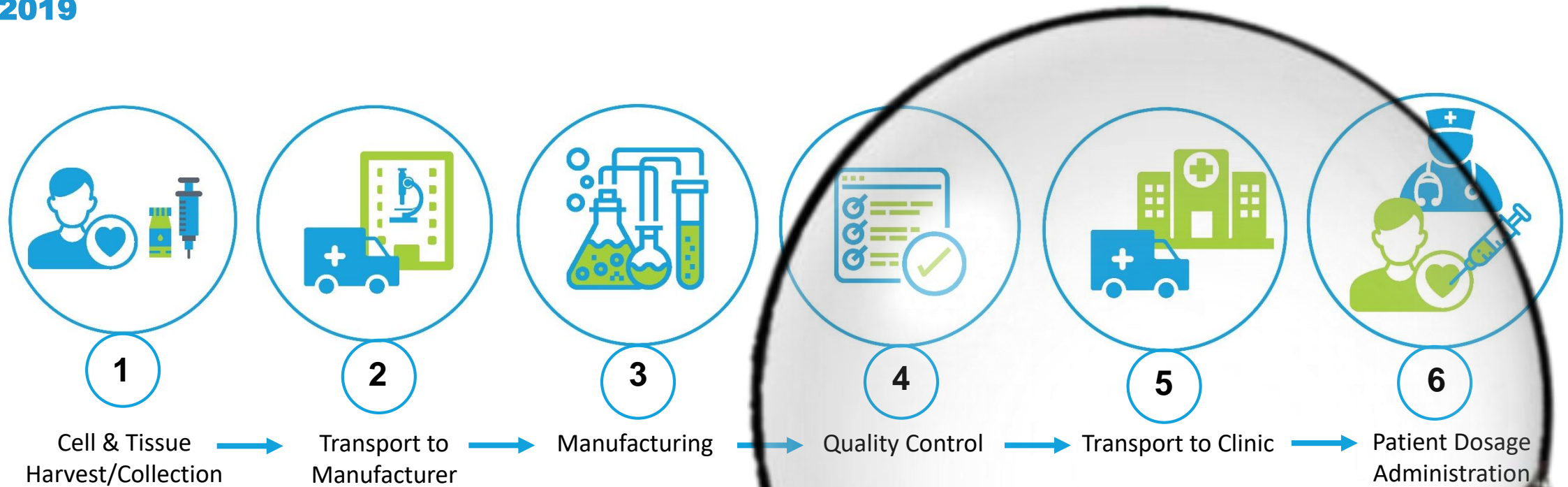
They are effective in reducing inflammation and pain

### IMMUNOMODULATORY

They help modulate the body's immune responses



# The process



# The problem



4  
Quality Control



5  
Transport to Clinic

## ATMP should be characterized with reference to its:

### Safety

- Sterility (bacterial & fungal sterility)
- Endotoxin
- Mycoplasma
- Tests for opportunistic viruses

### Potency

- Assay for biological function

### Purity

- Free of extraneous materials

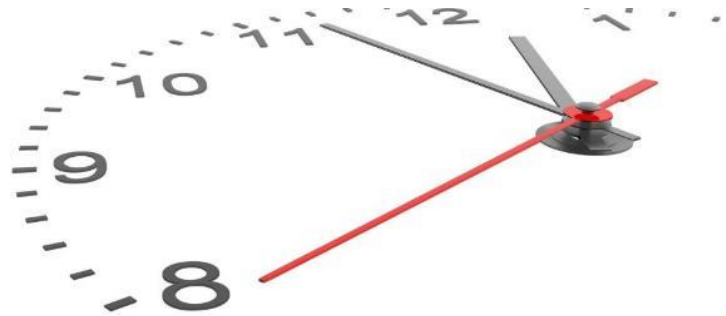
### Identity

- Specific test to distinguish it from others

**Minimally 72 hours** are needed to conduct QC tests and deliver the ATMP to bedside

**DO NOT OPEN**

# The time is the problem



ATMP should be stored for at least 72 hours

The storage of ATMPs in usual clinical-grade injection solutions will result in:

- **very low cell survival**
- **significant cell loss**
- **apoptosis**



**No efficiency  
of ATMP  
application**



## Challenge

ATMPs should be administered to patient in clinically safe vehicle solution, which should preserve viability of cells during at least 72 hours

# Clinical-grade solution for storage, transportation and administration of ATMPs

## Buffered trehalose solution (BTS)

Simple and efficient solution for the **cold storage** (2 - 8°C) of stem cells, preserving adequate cell viability for a period necessary to prepare QC studies and deliver the ATMP to a bedside



- Animal component-free, protein-free solution
- Supports storage and shipping stability for cells under hypothermic (2–8°C) conditions
- Reduces cellular stress response from chilling and re-warming of cells and tissues
- No additional components are needed
- Manufactured under cGMP conditions
- Consists of **pharmaceutically acceptable compounds** and can be used directly as a vehicle for the administration of ATMP to patient

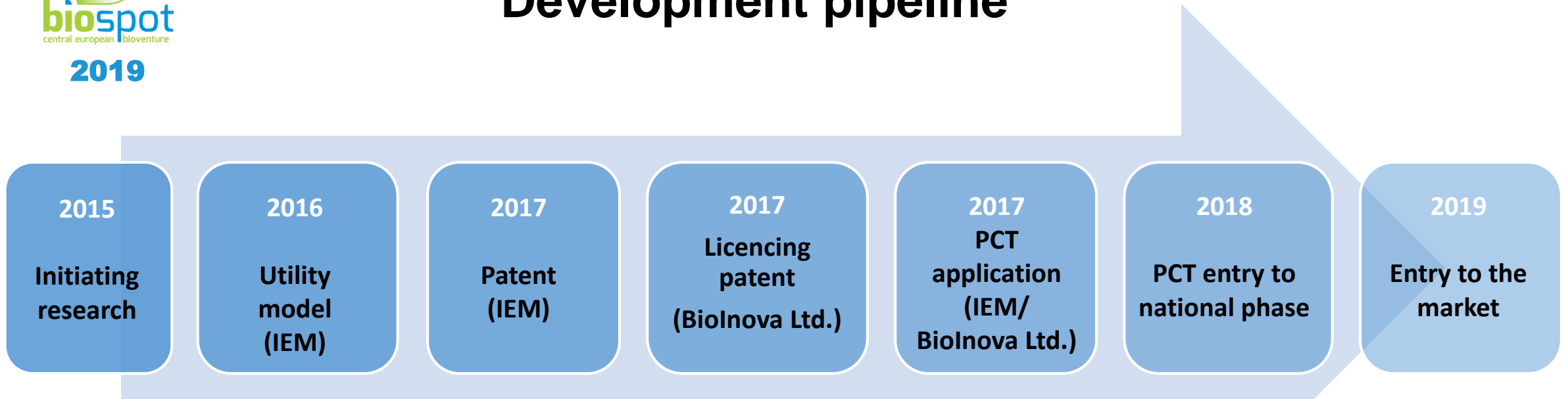
# Clinical-grade solution - What does it mean?



- ✓ Safety
- ✓ Reproducibility
- ✓ Cost-efficiency
- ✓ Improved efficiency of ATMP



# Development pipeline



**National Patent:** (2017) Petrenko, Y., Syková, E., Čejková, J., Vacková, I., Groh, T.: A device for storage, transport and application of stem cells. No. 306800. Licensed to Bioinova, Ltd.

**PCT/IB2017/052832 (Application):** IEM, Bioinova, Ltd. Petrenko, Y., Syková, E., Čejková, J., Vacková, I., Groh, T. Solution for the preservation, transport and application of stem cells.

**Publication:** Petrenko Y, Chudickova M, Vackova I, Groh T, Kosnarova E, Cejkova J, Turnovcova K, Petrenko A, Sykova E, Kubinova S. Clinically Relevant Solution for the Hypothermic Storage and Transportation of Human Multipotent Mesenchymal Stromal Cells. Stem Cells International, vol. 2019, Article ID 5909524, 2019. IF 3.989

# SWOT analysis

## Strengths



Simple and efficient solution

Can be applied directly to a patient as a vehicle solution for stem cells and other cell types

Low cost

Animal component-free, protein-free solution

## Weaknesses



Additional medical device certification

## Opportunities



Companies producing cells for clinical use and research & development, hospitals conducting clinical trials.

Large medical device / pharmacy manufacturers.

## Threats



Possible competition from companies that develop similar products.

# Main competitor on the market

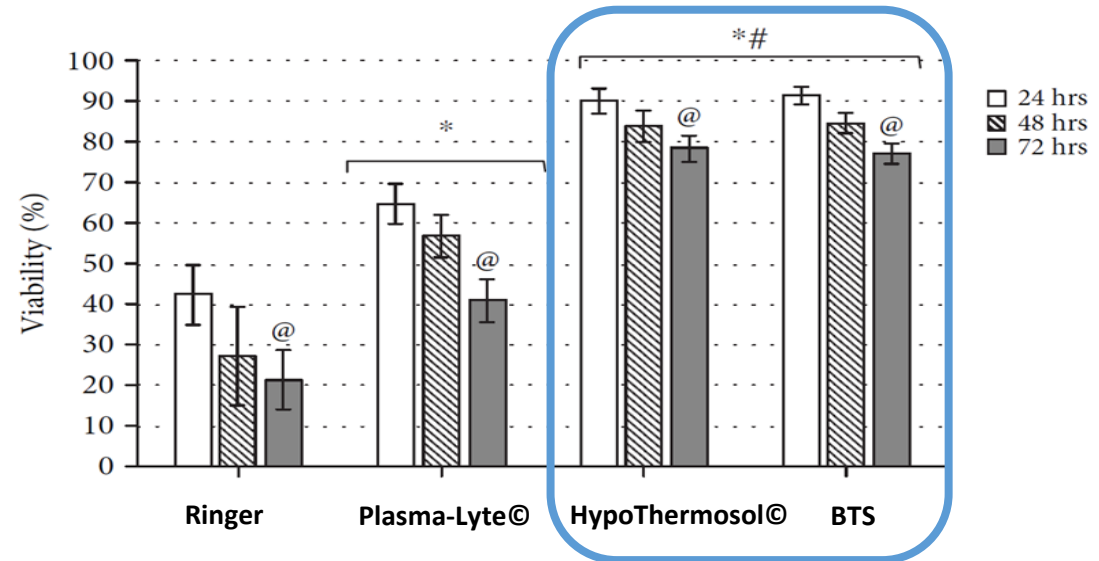


**BioLife SOLUTIONS®**

## HypoThermosol®

Hypothermic (2 - 8°C) preservation media for extended preservation of cells, tissues and organs.

	Hypothermosol FRS	BTS
<b>Number of components</b>	>12	5
<b>Osmolarity, pH</b>	350mOsm, pH 7,6	350mOsm, pH 7,2
<b>Efficiency</b>	<b>Identical</b>	



# Market analysis and marketing strategies

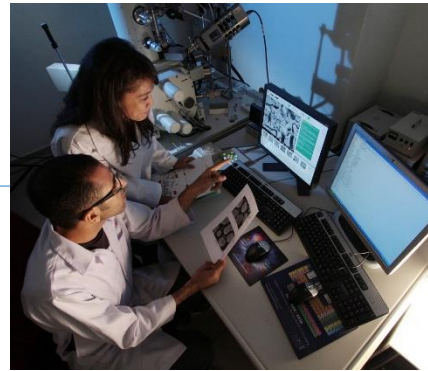
## Clinical-grade market



Implementation into clinical trials

Average 260 stem cells clinical trials starting each year

## Research-grade



Transport of cell lines between research centres. Storage during prolonged research assays

Thousands of research labs

## Licensing



Providing a license and guidelines to cell manufacturing companies

More than 100 companies in Europe

## Whole technology sale



Selling of whole technology to a large manufacturer

Possibility to combine all the strategies



**Looking for a strategic partnership to implement the aims and introduce the BTS into a market**

## Team



**Ústav  
experimentální  
medicíny AV ČR, v.v.i.**

EU Centre of Excellence

Dr. Yuriy Petrenko, PhD  
Dr. Irena Vackova, PhD  
Dr. Jitka Cejkova, PhD, DSc  
Prof. Eva Sykova, PhD, DSc  
Dr. Sarka Kubinova, PhD



**Bioinova**

Dr. Tomas Groh, PhD  
Dr. Peter Bauer, PhD

[yuriy.petrenko@iem.cas.cz](mailto:yuriy.petrenko@iem.cas.cz)