

XXIII Encuentro de Cooperación Farma-Biotech

28 de noviembre de 2023

PRS secretome tissue selective immunomodulatory complex (Biological medicinal product)

CÁTEDRA

en terapias avanzadas basadas
en secretomas celulares



Dr. Juan Pedro Lapuente





Content

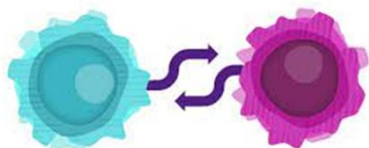
1. The Institution
2. The Product
 - a) Target Indications
 - b) Innovative mechanisms of action
 - c) Differential features facing the market
 - d) Current status of development
 - e) IPR protection
 - f) Pitfalls & Risks to be considered
3. Partnering Opportunities

OUR MISSION:

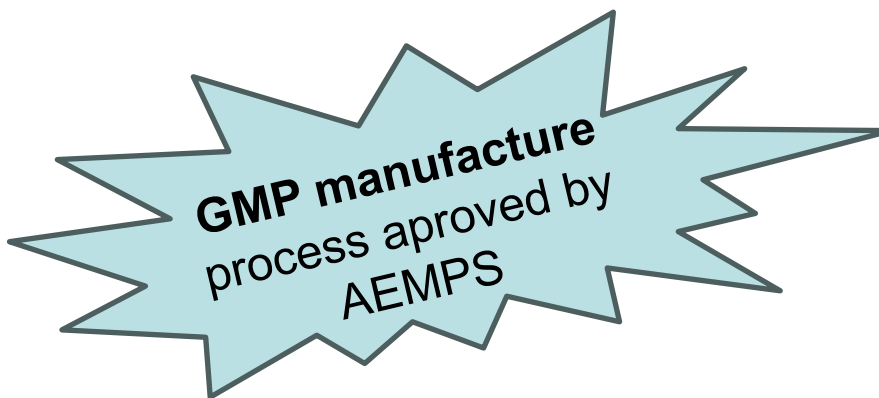
Peaches Biotech S.L. specialises in the generation of new complex biological drugs (secretome) through an innovative cell co-culture platform, capable of generating these drugs in the field of tissue-selective immunomodulation (Immunity Training Platform).

OUR VISION:

Peaches Biotech S.L. has developed tissue-selective secretome-based immunoregulatory drugs with high anti-inflammatory and anti-fibrotic efficacy, which enable an optimised regeneration process by regulating the communication between the innate and adaptive immune system.



Proprietary and patented immunity training platform to create multiple cell-free biologic drugs.



Own ATMPs GMP factory

Biologics drugs
Cell therapies drugs
Medical devices



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OUR COMPANY BOARD:



Juan Carlos de Gregorio

- Founder and CEO of PEACHES
- & CEO of Puleva Biotech
- Technical and Marketing Director Andrómaco
- 2005 Innovation Award IESE-Vocento-Ernst&Young
- Degree in Pharmacy. Galenic Specialization




Dr. Juan Pedro Lapuente

- Chief Scientific Officer of PEACHES
- Doctor of Medicine, Master in Transfusion and Advanced Cellular Medicine and Therapies from the University of Liège, Master in Sports Traumatology from the Catholic University of Murcia, Master in Molecular and Cellular Biology from the University of Zaragoza .



Ignacio Vega

- JOINS the shareholding as a financial partner.
- Founder and President of the Cardiva Group 1985, a Spanish medical equipment company with a turnover of more than 70 million euros per year.

 Peaches

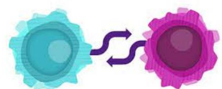
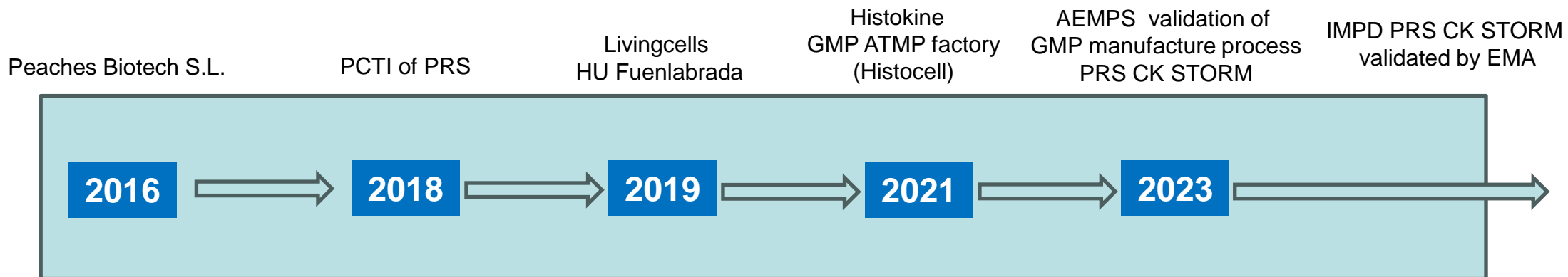


The company

 **Peaches**
BIOTECH

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OUR HISTORY:



Proprietary and patented immunity training platform to create multiple cell-free biologic drugs.



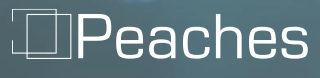
Own ATMPs GMP factory
Biologics drugs
Cell therapies drugs
Medical devices



GMP manufacture process aproved by AEMPS



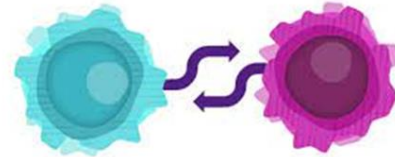
Cells master Banks certified by AEMPS



The company

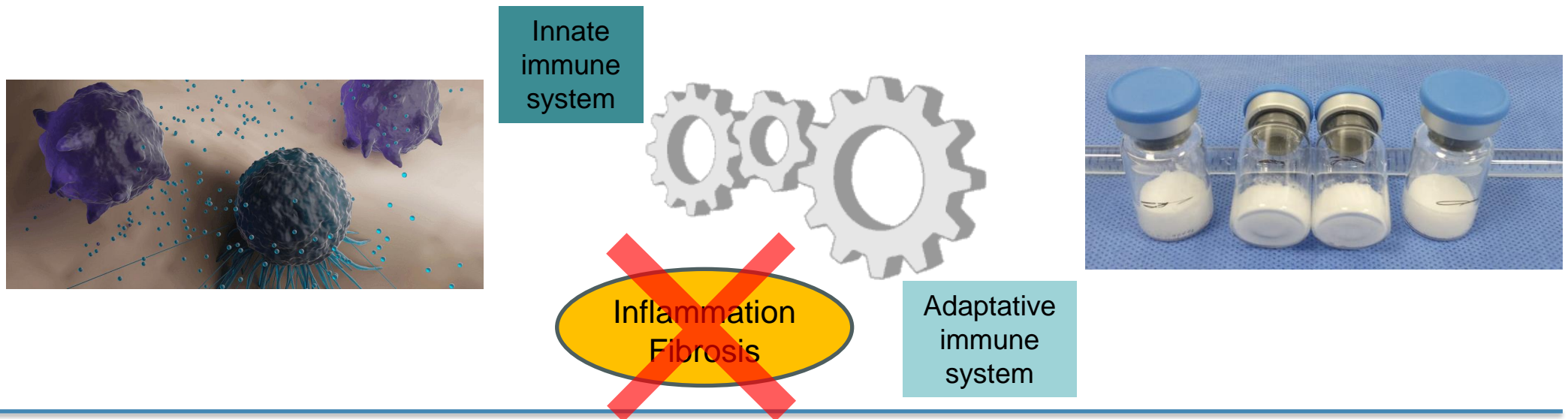


OUR INNOVATION:



Proprietary and patented immunity training platform to create multiple cell-free biologic drugs.

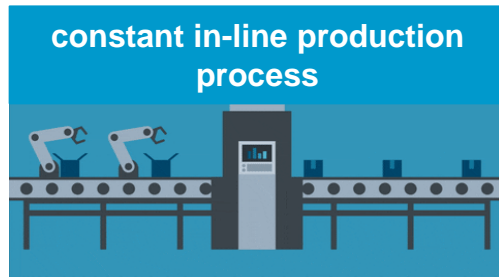
IMMUNITY TRAINING PLATFORM



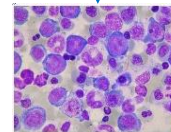
 Peaches

Innovation

OUR PRODUCT:



Leukopak

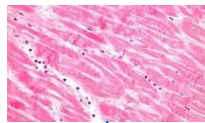


Isolation of monocytes



Monocyte culture

CO-CULTURE with Muscle cells



PRS MIOBOOST



Treatment of muscle ruptures.
Urinary incontinence recovery

CO-CULTURE with Schwann cells

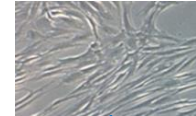


PRS NEUROPAIN



Treatment Neuropathic pain

CO-CULTURE with Tenocytes

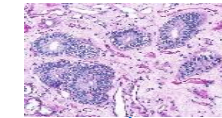


PRS TENOBOOST



Treatment of tendinosis

CO-CULTURE with Mesenchymal cells

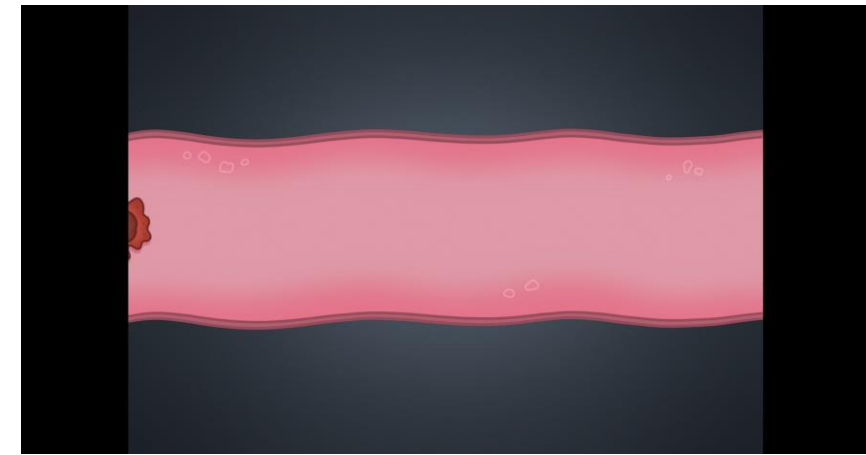


PRS CK STORM



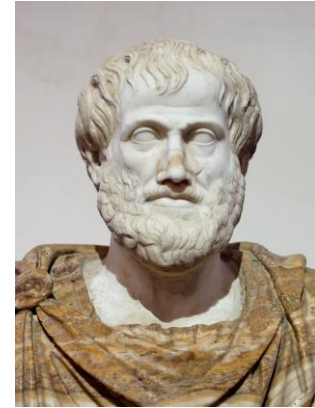
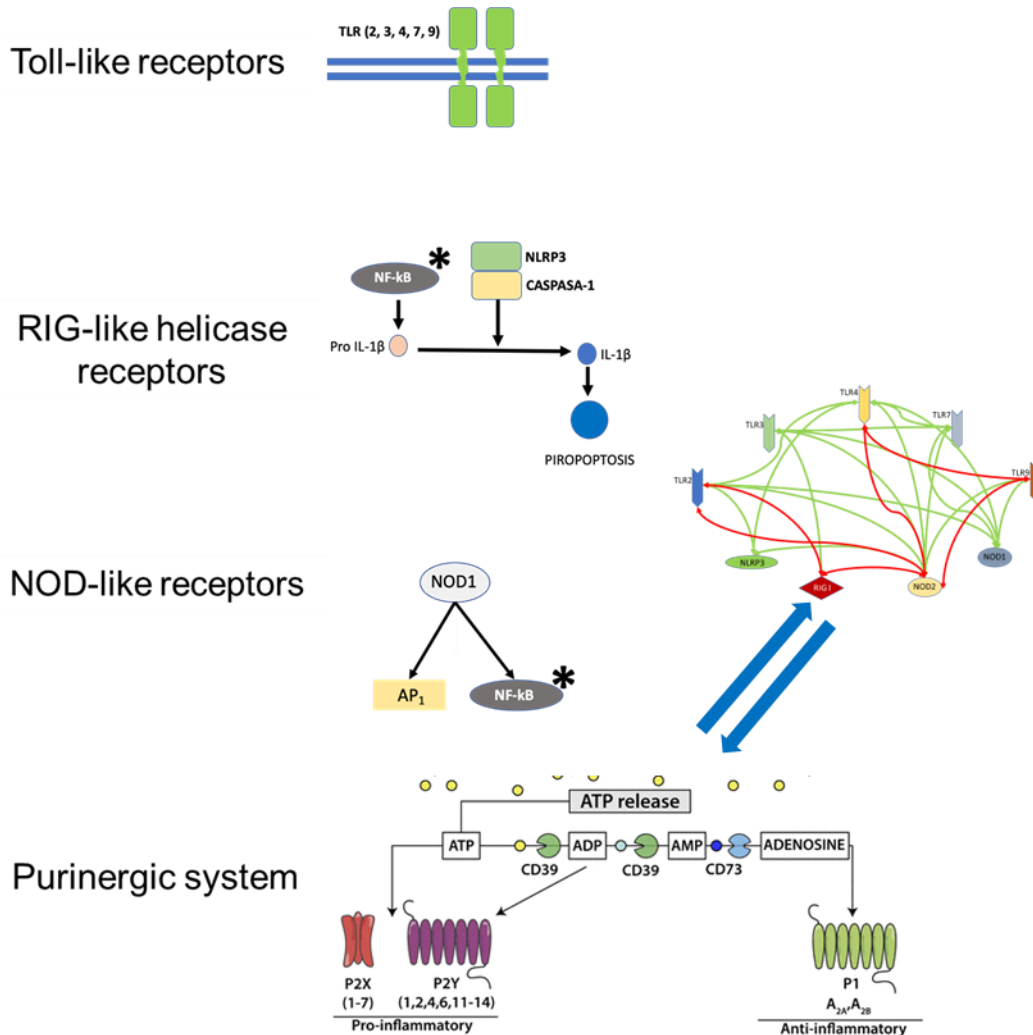
Cytokine Storm Treatment associated COVID-19,
associated pancreatitis, associated carTcell...
Crohn ulcers treatment

••• etc



The Product

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If cell therapies are safe and effective...

If the MoA of cell therapies is directly linked to the secretome they produce...

...Therapies based on the direct use of the secretome as a drug are also safe and effective.

The Mechanism of action (MoA)

MoA:

FIBROSIS: The common enemy in most inflammatory diseases

Tian B et al. NF- κ B mediates mesenchymal transition, remodeling and pulmonary fibrosis in response to chronic inflammation by viral RNA patterns. *Am J Respir Cell Mol Biol*. 2017 Apr;54(4):506-520.

Fujimoto H et al. Inhibition of Nuclear Factor- κ B in T Cells Suppresses Lung Fibrosis. *Am J Respir Crit Care Med*. 2007 Dec 15;176(12):1251-60.

Lu A et al. NF- κ B Negatively Impacts the Myogenic Potential of Muscle-derived Stem Cells. *Molecular Therapy* vol 20 no 3, 661-668 mar 2012

Chen S et al. RelA/p65 inhibition prevents tendon adhesion by modulating inflammation, cell proliferation, and apoptosis. *Nat Rev Gastroenterol Hepatol*. Cell Death and Disease (2017) 8, e2710

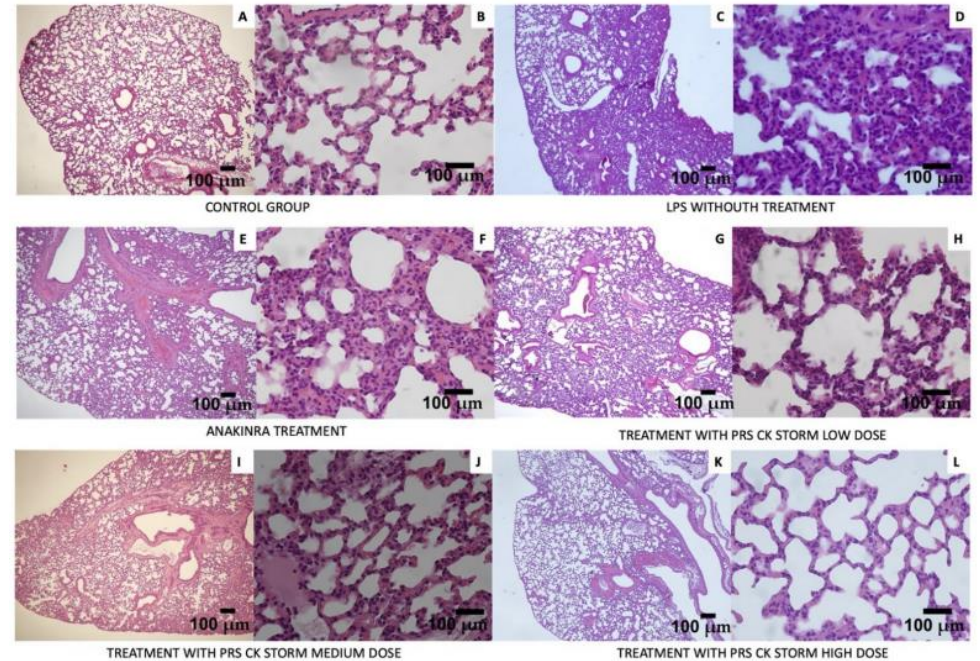
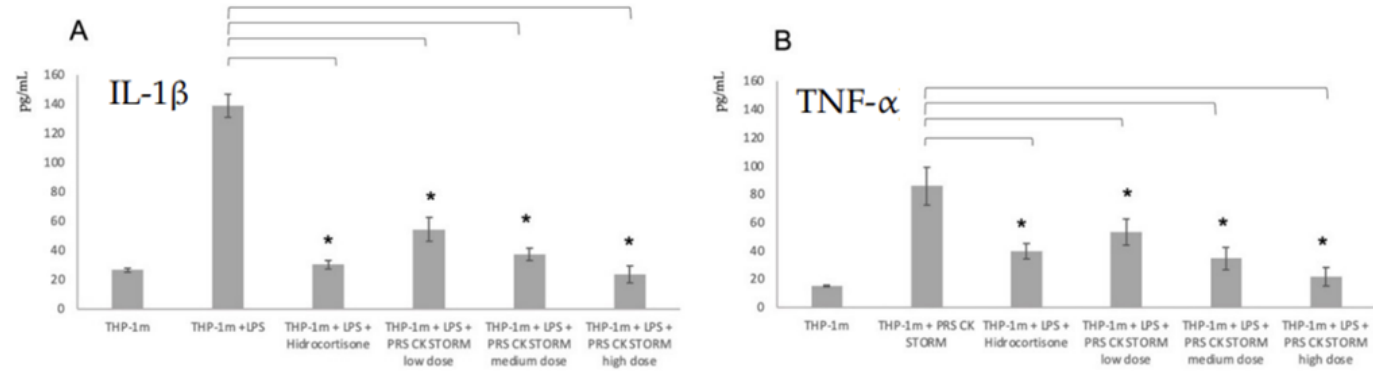
Ma H et al. Osteoarthritis is Prevented in Rats by Verbascoide via Nuclear Factor kappa B (NF- κ B) Pathway Downregulation. *Med Sci Monit*. 2020 Apr 6;26:e921276.

Nishimura R et al. Role of Signal Transduction Pathways and Transcription Factors in Cartilage and Joint Diseases. *Int J Mol Sci*. 2020, 21, 1340.

Taniguchi, K., Karin, M. NF- κ B, inflammation, immunity and cancer: coming of age. *Nat Rev Immunol* 18, 309-324 (2018).

Gleniec, K.A., Butler, L.M., Worthley, D.L. et al. Cancer-associated fibroblasts—heroes or villains?. *Br J Cancer* 121, 293-302 (2019).

Activation of **innate immunity** usually leads fibrosis (the common enemy in most of inflammatory diseases)



The biological composition of all PRS® controls and limits inflammation, favoring tissue regeneration, through a triple mechanism of immunomodulation tissue selective:

- 1) of the NF- κ B pathway
- 2) of the NLRP3 inflammasome
- 3) of the purinergic system



Non treated vs treated

EU trial number
2023-507700-32-00

 **vivotecnia**
researching for you

 **vivotecnia**
researching for you

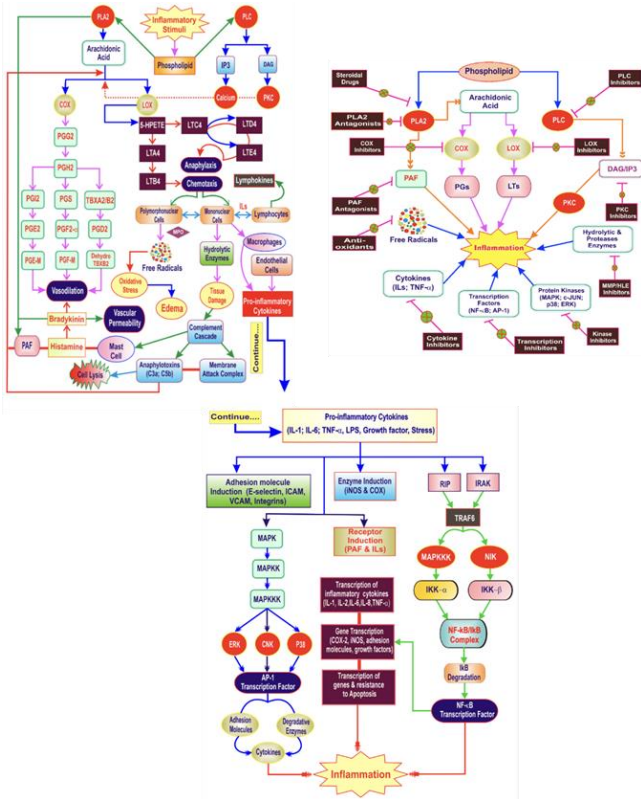
FINAL REPORT B-03327
14 Day Intravenous Toxicity Study of PRS CK STORM in the Sprague Dawley Rats with a 14 Day Treatment-Free Period
Volume I of IV

10th March 2022

FINAL REPORT B-03328
14 Day Intravenous Toxicity Study of PRS CK STORM in the Göttingen Minipig with a 14 Day Treatment-Free Period

Volume I of IV

31st March 2022



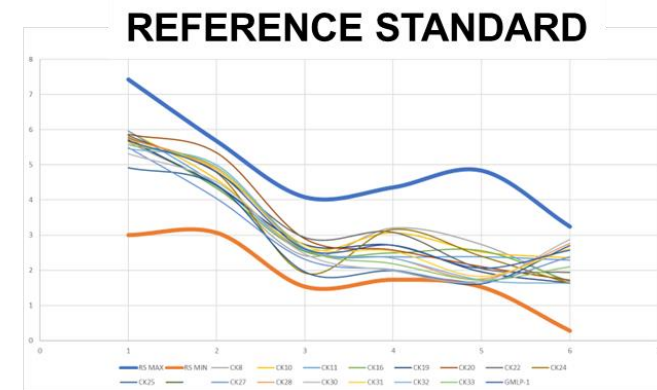
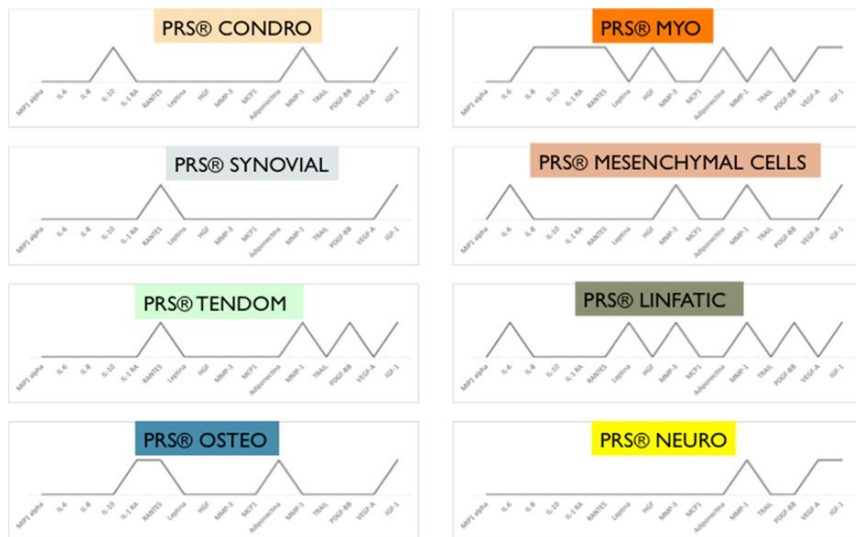
Biological medical complex drug

- Cell-free drug
- MoA multiple immunoregulatory properties
- Effects tissue-selective
- High safety and effectiveness
- Standardised product, highly characterised

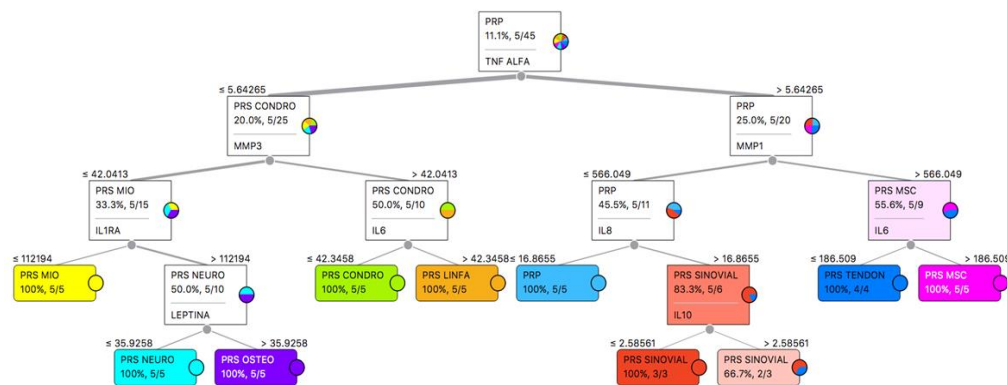
High industrial applicability

- Allogenic product
- Multiple therapeutic indications (inflammation and...)
- Easy transport and storage (freeze-dried product)
- Homogeneous batches with high reproducibility
- Low manufacturing costs
- GMP production protocols validated by AEMPS-EMA
- Factory ATMPs and biologics own GMP authorised by AEMPS

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- Specific potency test
- Cytokines, chemokines, and growth factors
- Microvesicles
- miRNA
- Aggregates
- Albumin
- Residual DNA
- Proteomic
- Lipidomic
- Adventitious viruses
- Sterility test
- Cytometric análisis of cells
- NGS and several bioinformatic análisis ...



Current status of development

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TIME PLANNING																
	2023				2024				2025				2026			
PRS CK STORM *	Preclinical	Preclinical	Preclinical	Phase I-IIa	Phase I-IIa	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IV	Phase IV	Phase IV	Phase IV
PRS MIO		Preclinical	Preclinical	Preclinical	Phase I-IIa	Phase I-IIa	Phase I-IIa	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IV	Phase IV	Phase IV	Phase IV	
PRS TENDON		Preclinical	Preclinical	Preclinical	Phase I-IIa	Phase I-IIa	Phase I-IIa	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IV	Phase IV	Phase IV	Phase IV	
PRS NEUROPATHIC PAIN		Preclinical	Preclinical	Preclinical	Phase I-IIa	Phase I-IIa	Phase I-IIa	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IIb-III	Phase IV	Phase IV	Phase IV	Phase IV	

EU trial number
 2023-507700-32-00



Preclinical BPL development



Phase I-IIa



Phase IIb-III



Phase IV

Current status of development

XXIII Encuentro de Cooperación Farma-Biotech



EP 3 719 119 A1

(19)  (11)  EP 3 719 119 A1

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(54) TISSUE-SPECIFIC GROWTH FACTORS, METHOD OF PRODUCTION AND USES THEREOF

(57) The invention describes a method for producing growth factors and/or cytokines, a composition and pharmaceutical composition comprising thereof and their uses. The compositions obtained by this method are suitable in medicine regenerative treatments, since are able to regenerate injured tissue. The compositions of the in-

vention may be stored for long periods until its use, avoiding any subsequent blood extraction from the cell-donor, being the stored growth factors and/or cytokines biologically active after storage. Moreover, the compositions may be applied in both autologous and allogenic treatments.

patent protection up
 to the year
 2040

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Declarations under Rule 4.17:
 — as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(i))

Published:
 — with international search report (Art. 21(3))



WO 2020/201404 A1

(54) Title: COMPOSITION FOR TISSUE REGENERATION, METHOD OF PRODUCTION AND USES THEREOF

(57) Abstract: The invention describes a method for obtaining a composition for tissue regeneration, comprising the following steps: providing M2-macrophages, co-culturing the M2-macrophages with tissue-specific cells in serum free medium, and collecting the supernatant of the co-culture. The compositions obtained by this method are suitable in medicine regenerative treatments, since are able to regenerate injured tissue. These products are sterile cell-free physiological aqueous solutions that show specific tissue concentration patterns to provide optimal tissue-specific regenerative effects. The compositions of the invention may be stored for long periods cryopreserved or lyophilized until its use, avoiding any subsequent blood extraction from the cell-donor, being the stored growth factors and/or cytokines biologically active after long-term storage. Moreover, the compositions may be potentially applied in both autologous and allogenic treatments.

IPR protection



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- ✓ **Biological Complexity**
- ✓ **Sterility**
- ✓ **Variability**
- ✓ **Quality control**
- ✓ **Development Timelines**
- ✓ **Intellectual Property**
- ✓ **Regulatory**
- ✓ **Scalability Industriousness**
- ✗ **Funding**

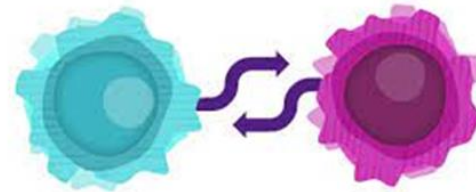


Pitfalls & risks to be considered

XXIII Encuentro de Cooperación Farma-Biotech



Own ATMPs GMP factory
 Biologics drugs
 Cell therapies drugs
 Medical devices



Proprietary and patented immunity training platform
 to create multiple cell-free biologic drugs with
 different clinical indications

CÁTEDRA
 en terapias avanzadas basadas
 en secretomas celulares

UAM Universidad Autónoma
 de Madrid

Peaches
 BIOTECH

patent protection up to
 the year
2040



Products manufactured under GMP
 conditions, fully characterised, standardised,
 lyophilised and allogeneic, with clinical trials
 in progress



High profitability at low risk

Partnering opportunities

Peaches
 BIOTECH



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