

## Press Release

Reims, August 31, 2023



## AUTHORIZED AS A PHARMACEUTICAL COMPANY BY FRENCH REGULATORY AUTHORITIES (ANSM), CREAPHARM BIOSERVICES EXPANDS ITS SCOPE TO INCLUDE ADVANCED THERAPY MEDICINAL PRODUCTS

On the occasion of its third anniversary, the biobank which integrated CREAPHARM GROUP as CREAPHARM BIOSERVICES, got its Manufacturer's Authorisation from the French National Agency for Medicines and Health Products (ANSM\*) on August 21st 2023.

### A KEY LINK FOR THE CELL & GENE THERAPY STAKEHOLDERS

With a surge of 222 groundbreaking clinical trials launched in 2022 (1), the Cell & Gene Therapy (C&GT) sector continues to gain momentum. As a vital pillar in this transformative landscape, CREAPHARM BIOSERVICES has achieved a remarkable milestone. The rigorous scrutiny conducted by the French Regulatory Authorities (ANSM) during file assessment has underscored CREAPHARM BIOSERVICES' unwavering commitment and strict adherence to Good Manufacturing Practices (GMP). This achievement paves the way for CREAPHARM BIOSERVICES to extend its services, positioning itself as a key player in the **storage, pharmaceutical packaging, QP-Release, and distribution of both investigational and market-approved Advanced Therapy Medicinal Products (ATMPs)**

### THE EXPERTISE IN ULTRA-COLD STORAGE TO SERVE ATMPs

Since 2020, CREAPHARM has provided pharmaceutical laboratories, biotech companies and research centers with ultra-secured biostorage solutions, **from -196°C to ambient temperature**. For 17 years, Frédéric Malboze has been an expert in cryopreservation and was a founder of this first French biobank. Thanks to his team and state-of-the-art facilities, he is going to **optimize the complex supply chain for new-generation biomedicines**.

" Our focus on patient care and safety is paramount. This Manufacturer's Authorization exemplifies our dedication to ensuring that patients receive Cell & Gene therapies with the utmost efficiency and reliability. "

*Frédéric Malboze, General Director CREAPHARM BIOSERVICES*

## CREAPHARM BIOSERVICES

Since 2020, the private biobank CREAPHARM BIOSERVICES has partnered with Pharma, Biotechs and Institutional players, providing them with highly-secure biobanking & biorepository solutions from ambient to -196°C.

- BIOSPECIMEN MANAGEMENT
- ATMPs SUPPLY CHAIN
- BIOSTORAGE & LOGISTICS
- CONSULTING & AUDIT
- TRAINING CENTER
- DISASTER PREPAREDNESS

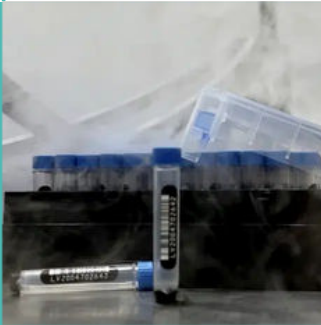


\* Agence Nationale de Sécurité du Médicament et des Produits de Santé

(1) Source: The Cell And Gene Therapy Sector In 2023: A Wave Is Coming – Are We Ready?  
[invivo.pharmaintelligence.informa.com](https://www.invivo.pharmaintelligence.informa.com)

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### IMPORTATION, PACKAGING AND WORLDWIDE DISTRIBUTION of ATMPs

- Cell therapy products
- Gene therapy products
- Tissue engineered products

" This authorization testifies to the CREAPHARM BIOSERVICES' commitment to adhere to GMP standards, ensuring the quality and reliability of products at every stage of the supply chain. By combining comprehensive traceability with a risk-based approach, we ensure the effective and secure management of Cell & Gene therapy medicinal products, thereby contributing to ensuring broader patient access to these new therapies. "

*Meriem Dhib Charfi, Responsible Pharmacist CREAPHARM BIOSERVICES*

### AN UNPARALLELED STRUCTURE

- A state-of-the-art plant, compliant with GMP requirements. As a Pharmaceutical Company, the Centre of Biological Resources is certified ISO 9001, ISO 20387 & NF S96-900. The company is authorized by the French National Agency for Medicines and Health Products (ANSM) for storage of therapeutic tissues & cells, under the article L.1243-2 of the French Public Health Code (CSP)
- Staff and products are secured at any moment: redundancy of security systems, communication systems, lifting machine...
- Expertise in cold-chain management: a valuable asset, especially during complex operations such as secondary packaging or labelling in vapour phase liquid nitrogen.

