MUNI | CREATIC

Central European Advanced
Therapy and Immunotherapy Centre

CREATIC: From Widening to Excellence – and Beyond

Regina Demlová, CREATIC CoE Director

CZEDER Conference, 23.11.2026, Prague

CREATIC CoE, FACULTY OF MEDICINE, MASARYK UNIVERSITY











CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC and Section 13, paragraph 2, letter a, point 3 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals), as amended.

The competent authority of the Czech Republic confirms the following:

The manufacturer:
Masarykova univerzita
Žerotínovo nám. 617/9
601 77 Brno

Site address:
Advanced Cell Immunotherapy Unit (ACIU), MU
Kamenice 5
625 00 Brno

Has been inspected under the national inspection programme in connection with manufacturing authorisation no 17692/2/INS/06, last variation no sukls125048/2015 issued on 26.10.2015 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: Section 57 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals), as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12.11.2015, it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[1].

[1] These requirements fulfil the GMP recommendations of WHO.

Part 2
☒ **Human Investigational Medicinal Products**

1 MANUFACTURING OPERATIONS
1.1 Sterile Products
1.1.1 Aseptically prepared (processing operations for the following dosage forms)
1.1.1.4 Small volume liquids

1.1.3 Batch certification

1.3 Biological medicinal products
1.3.1 Biological medicinal products (list of product types)
1.3.1.3 Cell therapy products

1.3.2 Batch certification (list of product types)
1.3.2.3 Cell therapy products

1. 5 Packaging
1.5.2 Secondary packing

1.6 Quality control testing
1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate:
1.3.1.3 Cell therapy products –

- autologous and alogenous investigational medicinal products based on in vitro cultivation of immunocompetent cells
- autologous and alogenous investigational medicinal products based on cultivation of hematopoietic and non-hematopoietic stem cells and immunocompetent cells including their depletion

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

TEAMING FOR EXCELLENCE, THE CALL AND CREATIC

A European instrument to build new Centres of Excellence – our project in advanced therapies

WHAT IS TEAMING?

A Horizon Europe action that supports the **creation of new Centres of Excellence** or the **upgrading of existing ones** in lower R&I performing countries, through long-term **partnerships with leading European institutions**.

THE CALL – KEY FEATURES

- Main goal: improved **access to excellence** for widening countries
- Budget: up to **€15 million** for 6 years
- Complementary national co-funding: **€15 million**
- Research component: ≤ **10%** of the HE grant

MUNI | CREATIC
Central European Advanced Therapy and Immunotherapy Centre

OUR TEAMING PROJECT:

Building a Centre of Excellence in Advanced Therapies

Fraunhofer IZI | UNIVERSITÄT LEIPZIG | UNIVERSITY OF COPENHAGEN

OUR THEME: TOWARDS A RESEARCH STRATEGY



OUR FOCUS

- ✓ Development of ATMPs (cell and gene therapies)
- ✓ Translational and clinical evaluation
- ✓ Personalised approaches in cancer and rare diseases
- ✓ From research to patient access

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

TEAMING FOR EXCELLENCE, THE CALL AND CREATIC



gene therapy medicinal products



somatic cell therapy medicinal products



tissue-engineered products



combined ATMP (medical device)

Invitation to grant preparation: **12 projects**

Budget: max. €15 mil.

Duration: max. 72 months

Horizon Europe Teaming for Excellence Stage 2 2022

Number of proposals submitted: **31**

Number of above-threshold proposals: 27

Horizon Europe Teaming for Excellence Stage 1 2021

Number of proposals submitted: **116**

Number of above-threshold proposals: 32

CREATIC MISSION AND VISION

Our Mission

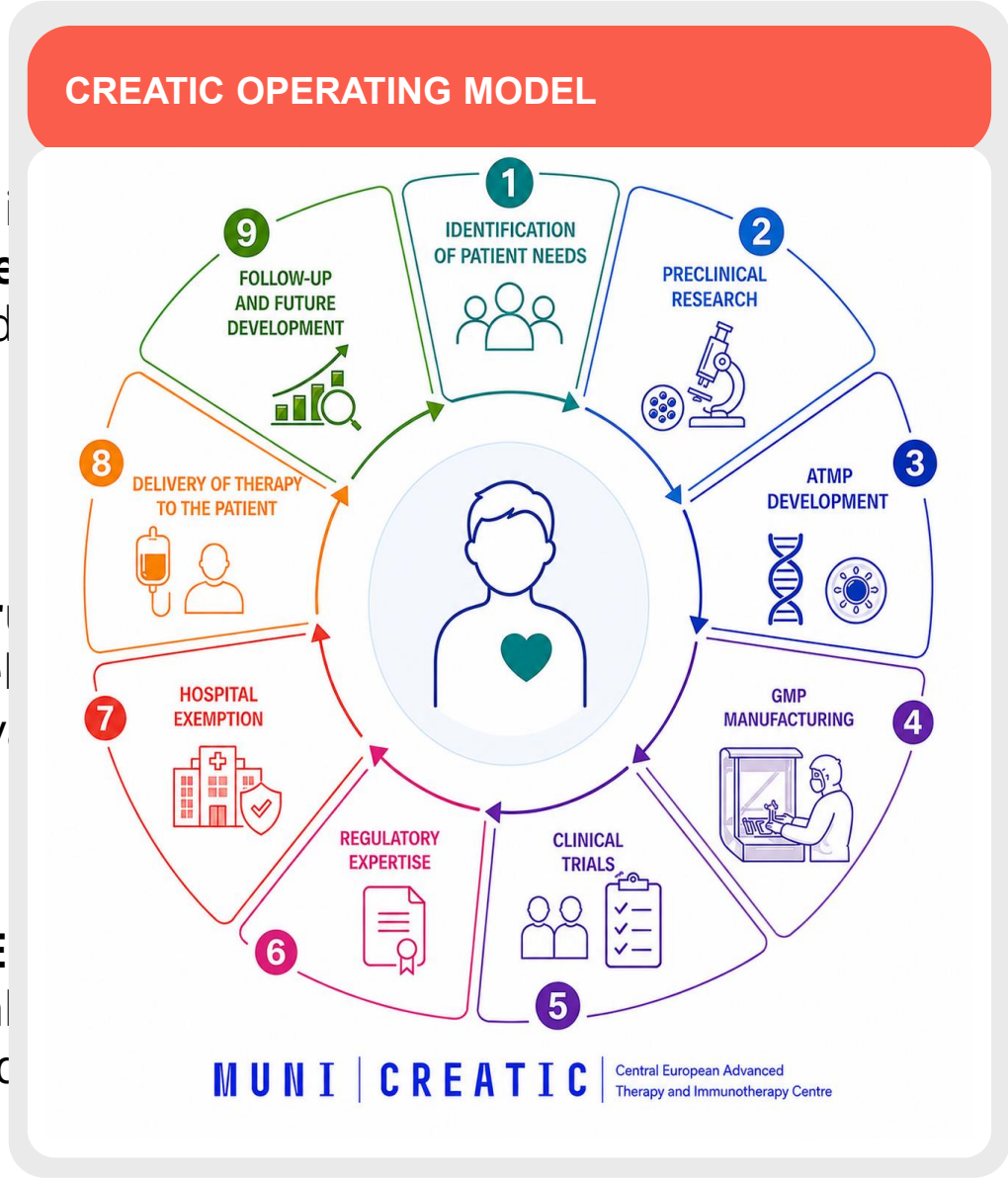
To translate cutting-edge biomedical science i
therapies by combining **scientific excellence**
integration and innovation, focusing on ind
are weak but patient need is high.

Our Vision:

By 2030, CREATIC will be **Central Europe's tr**
across Central Europe as a benchmark model
pipeline of therapies, spin-offs, and societal v

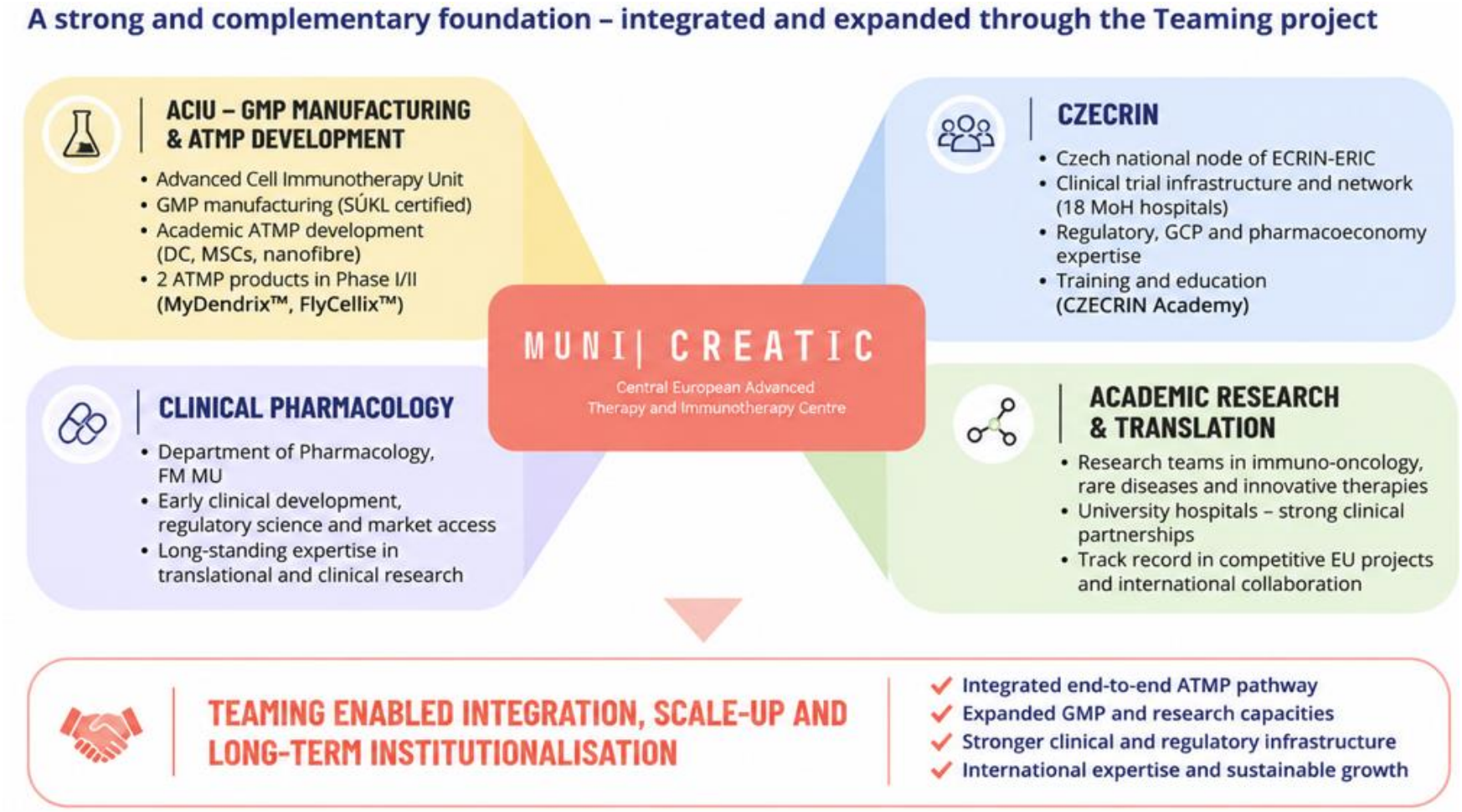
A Key Hub for Central Europe

Located at a strategic point in **Central E**
research, and clinical expertise, fostering colla
the development and deployment of advanced



Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

BUILT ON PREVIOUS STRONG EXPERTIZE



Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

WHAT TEAMING MADE POSSIBLE

Strategic partnership and synergies across Europe



A NEW CENTRE OF EXCELLENCE (SINCE 2024)

Expanded research capacity
Three research programmes, eight teams, new international group-leader calls

State-of-the-art infrastructure
Reconstructed C03 and specialist facilities, including GMP manufacturing

Transfer of expertise and know-how
Joint development, training and mobility with European partners

Integration and translational pathway
From research to GMP production, clinical evaluation and patient access

THE CREATIC OPERATING MODEL



EUROPEAN ADDED VALUE

- ✓ Access to world-leading expertise
- ✓ Accelerated development and higher quality of ATMPs
- ✓ Stronger European research and innovation networks
- ✓ A sustainable, internationally competitive Centre of Excellence in the CEE region

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

CREATIC RESEARCH PROGRAMMES

RESEARCH PROGRAMME 1
CREATIC-RD (RARE DISEASE)

RG1 Human Translational Genomics
Ondřej Slabý, PhD
joint RG – Dept. of Biology, Faculty of Medicine, MU

RG2 Undiagnosed Pediatric Patients
Kateřina Slabá, MD, PhD
clinical, joint RG – Dept. of Pediatrics, Faculty of Medicine, MU, Univ. Hospital Brno

RG3 ATMPs for Rare Diseases
Lenka Zdražilová Dubská, PhD

RESEARCH PROGRAMME 2
CREATIC-IO (IMMUNO-ONCOLOGY)

RG4 Pediatric Cancer Clinical Investigation
Jaroslav Štěrba, MD, PhD
clinical, joint RG – Dept. of Pediatric Oncology, Faculty of Medicine, MU, Univ. Hospital Brno

RG5 Cancer Immunotherapy Resistance
Lenka Bešše, PhD
joint RG – Dept. of Biology, Faculty of Medicine, MU

RESEARCH PROGRAMME 3
CREATIC-INNO (INNOVATIONS)

RG6 Innovative Models for Vision Research
Tomáš Bárta, PhD
joint RG – Dept. of Histology and Embryology, FoM, MU

RG7 Models for Neurodegenerative Diseases
Dáša Bohačiaková, PhD
joint RG – Dept. of Histology and Embryology, FoM, MU

JRG8 Applied Medical Microbiology
Martina Lengerová, PhD
joint RG – Dept. of Laboratory Medicine, FoM, MU, Univ. Hospital Brno

Further international research-group calls
Profiles aligned with the CREATIC strategy and Business Plan

HR EXCELLENCE IN RESEARCH

3 research programmes
8 named research teams
Further international group-leader calls planned

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

CREATIC KNOWLEDGE EXPERTIZE UNITS

REGULATORY KNOWLEDGE

Regulatory assessment & evaluation

Systematic review of product documentation, compliance verification, identification of regulatory risks.

Product identification & opportunity mapping

Assessment of product potential, therapeutic positioning, and unmet medical needs.

Regulatory strategy (comprehensive or phase-specific)

Tailored roadmaps for development phases (preclinical, clinical, registration, post-marketing).

Product Development Plan (PDP)

Integration of regulatory, clinical, and quality aspects into a unified development pathway.

DATA EXPERTISE

Data management & biostatistics

Governance of clinical, preclinical and real-world data

Advanced statistical modelling and predictive analytics

Open data principles & FAIR standards

Data sharing frameworks ensuring Findability, Accessibility, Interoperability, Reusability. Controlled sharing and dataset release after applicable clearance.

Advanced visualisation & reporting

Visual analytics supporting decision-making by regulators, HTA bodies, and payers

Evidence generation for decision-making

Integration of clinical, regulatory, epidemiological and real-world evidence

Support for HTA dossiers, market access strategies and reimbursement negotiations

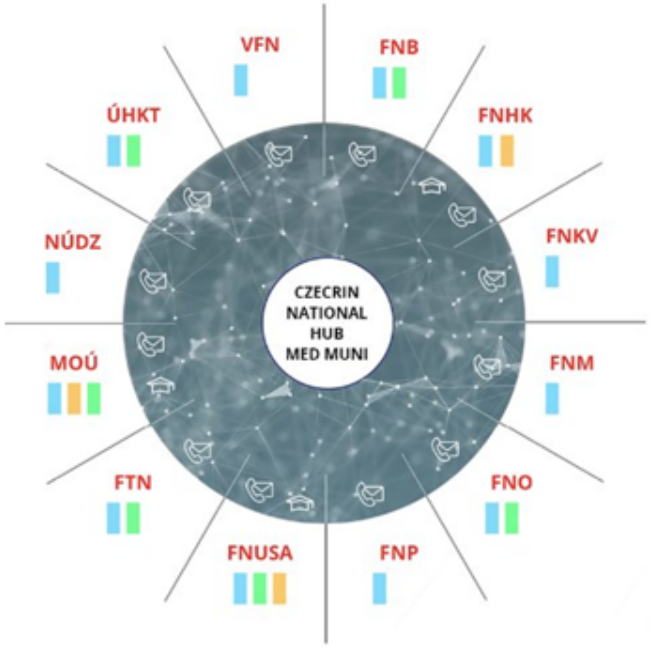
Financováno Evropskou unií

Ministerstvo školství, mládeže a tělovýchovy

CLINICAL RESEARCH INFRASTRUCTURE

NATIONAL CLINICAL TRIALS CENTER & LOCAL HUBS

A national clinical-research network connects hospital teams, disease-oriented expertise and specialised trial support.



CZECRIN Local HUBs:

FNB	University Hospital Brno
FNHK	University Hospital Hradec Králové
FNKV	University Hospital Královské Vinohrady
FNM	University Hospital Motol
FNO	University Hospital Ostrava
FNP	University Hospital Plzeň
FNUSA	St. Anne´s University Hospital Brno
FTN	Thomayer University Hospital
MOÚ	Masaryk Memorial Cancer Institute
NÚDZ	National Institute of Mental Health
ÚHKT	Institute of Hematology and Blood Transfusion
VFN	General University Hospital in Prague

The presence of Clinical Trials Unit

Leading a Disease-Oriented Network

Certificate for FIH CT/Phase I Unit

CZECRIN HUB contact person

CZECRIN Academy parts

CZECRIN
CZECH CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

CREATIC PRODUCTION FACILITY (CreProFa)

COMPREHENSIVE FACILITIES

Advanced Cell Immunotherapy GMP Unit (ACIU)

Gene Advanced Therapy GMP Unit (GATU)

Biotechnology Protein GMP Unit (BiGU)

QC and R&D Laboratories | Storages & Warehouses

CLEAN ROOMS (1,000 SQ. M)

GMP-certified areas with cleanliness classes A, B, C, D & CNC (Controlled Not Classified)

GMP COMPLIANCE

Validated processes & monitoring

High-level qualification of staff

Advanced analytical & microbiological methods

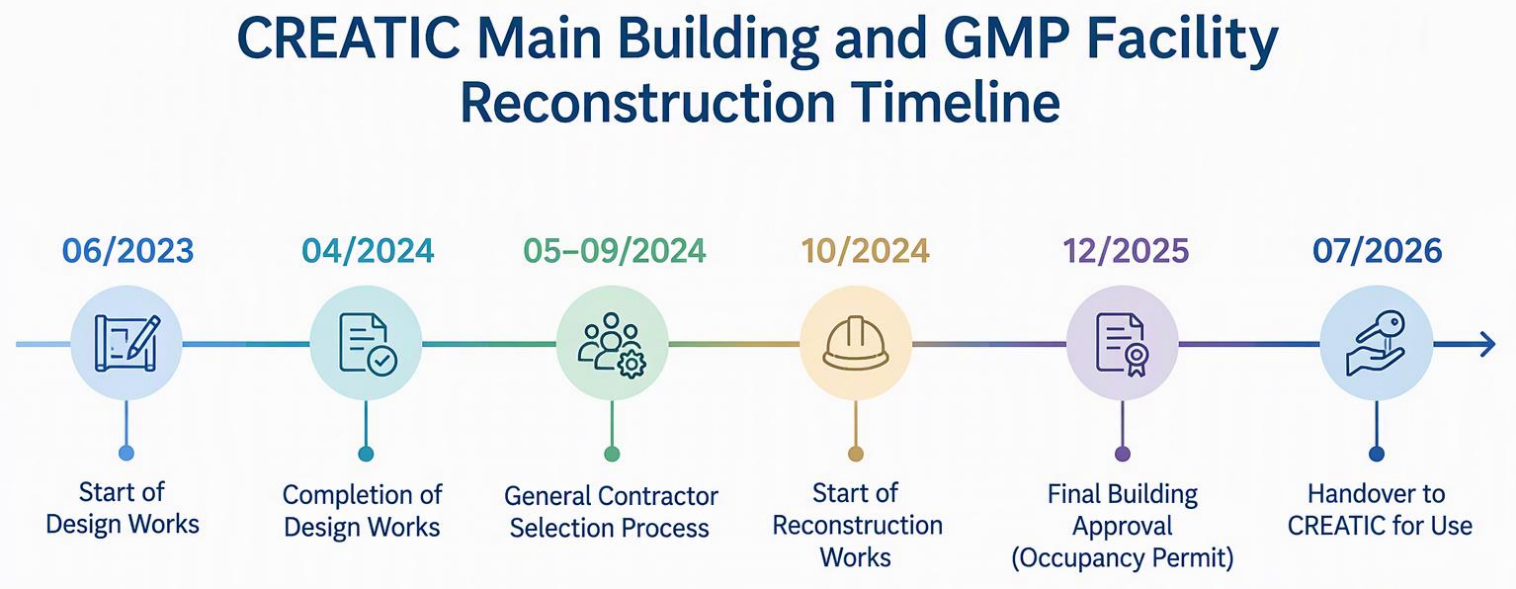
Cutting-edge equipment and knowledge

Cutting-edge facilities offer a comprehensive environment for advanced cell and gene therapy research, development and GMP production, designed to meet the highest standards of quality and safety.

Financováno Evropskou unií

Ministerstvo školství, mládeže a tělovýchovy

CREATIC PRODUCTION FACILITY (CreProFa) RECONSTRUCTION



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of

Part 2

☒ Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile Products





Section 57 of the Act No 378/2007 Coll., on Pharn and on Amendments to Some Related Acts (tl Pharmaceuticals), as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12.11.2015, it is considered that it complies with The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[1].

[1] These requirements fulfil the GMP recommendations of WHO.

products based on in vitro cultivation of immunocompetent cells

- autologous and alogenous investigational medicinal products based on cultivation of hematopoietic and non-hematopoietic stem cells and immunocompetent cells including their depletion

KNOWLEDGE VALORIZATION UNIT (KEVIN)

KNOWLEDGE VALORISATION

Translating the research activities of CREATIC into products or services with real economic, social or ethical value.

Development and production of ATMPs prepared on a non-routine basis according to Regulation (EC) No 1394/2007 („hospital exemption", HE ATMP)

Market access for HE ATMP (fair pricing, reimbursement, sustainable financing)

Real availability of medicines for advanced therapies for patients with rare diseases

INTELLECTUAL PROPERTY

Building an intellectual property management strategy to capitalise on the findings of CREATIC

Trade marks for CREATIC products and services

Freedom to operate for R&D

Management strategy for intellectual assets

Financováno Evropskou unií

Ministerstvo školství, mládeže a tělovýchovy

KNOWLEDGE VALORIZATION UNIT (KEVIN)
THE INTEGRATED TRANSLATIONAL PIPELINE

One pathway, named stages, shared capacities — and where the portfolio sits on it today

Disease mechanism & target identification	Candidate design & selection	Preclinical proof of concept	GMP manufacturing & quality control	Clinical development	Patient access & evidence
Research Groups	Research Groups + advanced partners	Research Groups, patient-derived models	CREPROFA	CZECRIN + clinical Research Groups	Knowledge Valorization Unit and Centre-level expertise

Where the ATMP programmes sit today

- **TIL** TRL 2/3
- **Mesothelin CAR-T** TRL 2/3
- **GD2 CAR-NK** TRL 3/4
- **GD2 CAR-Mφ** TRL 3
- **MSC** TRL 6
- **MyDendrix®** TRL 9

Two points this picture is meant to make

The pathway has been walked end to end. One ATMP programme has already travelled the whole way to patients, which means the route is not a plan, it exists and it has been used.
The portfolio behind it is early, as it should be. Four of six ATMP programmes are in early stages. At M36 of a six-year Centre, that is the expected shape. The objective for RP3 is to move the existing programmes one stage to the right, not to add new ones.

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

HOW THE PIPELINE WORKS IN PRACTICE: **MyDendrix®**



The hand-offs are the hard part

The step from a Research Group to a GMP facility, and from there into a clinical trial, is where academic advanced therapies usually stop. Here they did not.

The same groups re-enter later

RG4 appears at the start, as the source of the clinical question, and again at the trial. That is what the matrix model means in practice.

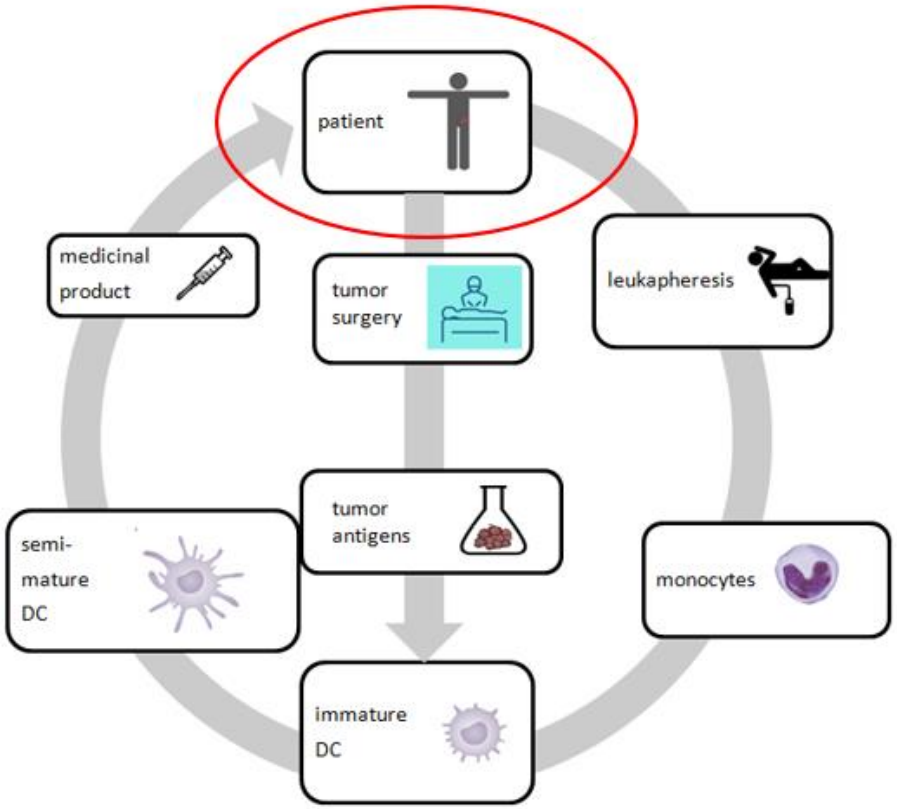
It is now a template

The same approach is being applied to the other programmes in the portfolio, each entering the pathway at a different stage.

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

EXCELLENCE MUST DELIVER IMPACT: **MyDendrix®**

Hospital Exemption approved by SÚKL as the first in the Czech Republic (March 2026)



REGULATORY DECISION (SÚKL)

STÁTNÍ ÚSTAV PRO KONTROLU LÉČIV
Šrobárova 48
100 41 Praha 10
Telefon: +420 272 185 111
Fax: +420 271 732 377
E-mail: posta@sukl.cz
Web: www.sukl.cz

ADRESÁT
CREATIC Production Facility, Centrum excelence CREATIC,
Lékařská fakulta, Masarykova univerzita,
Kamenice 5,
625 00 Brno

ADRESA PRO DORUČENÍ
Lékařská fakulta, Masarykova univerzita,
Kamenice 5,
625 00 Brno

Sp. zn.
sukls350180/2025

Vyřizuje/linka
MUDr. Alice Němcová /817

Datum
12.03.2026

ROZHODNUTÍ

Státní ústav pro kontrolu léčiv, se sídlem Šrobárova 49/48, 100 00 Praha 10 (dále jen „Ústav"), jako orgán příslušný k rozhodnutí podle § 13 odst. 2 písm. l) zákona č. 378/2007 Sb., o léčivech a změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (dále jen „zákon o léčivech") **rozhodl** v souladu s § 67 a násl. zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů (dále jen „správní řád"), v řízení o povolení nemocniční výjimky pro léčivé přípravky pro moderní terapie vedeném podle § 49a zákona o léčivech (dále jen „nemocniční výjimka") o žádosti o povolení nemocniční výjimky pro léčivé přípravky pro moderní terapie společnosti **CREATIC Production Facility, Centrum excelence CREATIC**, IČ: **00216224** se sídlem **Lékařská fakulta, Masarykova univerzita se sídlem Kamenice 5, 625 00 Brno**, (dále jen „účastník řízení") týkající se nemocniční výjimky pro léčivé přípravky pro moderní terapie s názvem autologní dendritické buňky produkující interleukin 12 (dále jen „předmětný přípravek")

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

INTEGRATED PORTFOLIO ASSESSMENT – BUSINESS DEVELOPMENT PANEL

Assessment	Decision evidence
Patient and clinical value Market, competition and outlooks	Target indication, unmet need and clinical relevance, market situation, trends, RA pathways development, scientific trends
Development feasibility	Scientific maturity, manufacturing readiness and regulatory route
Protection and partnership	Background / foreground IP, freedom to operate and partner contributions
Resources and returns	Development budget, milestones, risks and realistic income potential

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

LONG-TERM IMPACT, SUSTAINABILITY AND ECOSYSTEM

A diversified, connected and European ecosystem for long-term impact

A SUSTAINABLE CENTRE: THREE OPERATING PILLARS

Services and education
Clinical research, regulatory, GMP, data and training services

Innovation valorisation
Products, IP, licensing and technology transfer

Competitive & public funding
National and European research and infrastructure funding



FROM RESEARCH TO PATIENTS

MyDendrix™ demonstrates the end-to-end pathway
Research → GMP production → clinical evaluation → patient access

Our goal
To make this pathway reproducible for other advanced therapies

STRATEGIC PARTNERSHIP AND EUROPEAN COLLABORATION

Fraunhofer IZI | UNIVERSITÄT LEIPZIG | UNIVERSITY OF COPENHAGEN

- ✓ Transfer of know-how and best practice
- ✓ Joint development and training
- ✓ Long-term European research networks

LOOKING AHEAD: EUROPEAN CONTINUITY AND IMPACT

- ✓ Integration into future EU initiatives (e.g. EU4Health, Innovative Health Initiative)
- ✓ A resilient, internationally competitive Centre of Excellence in the CEE region

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

SERVICE PORTFOLIO AND COMMERCIAL TRACTION

Service area	Reported traction	Next conversion step
Clinical research	14 projects, ~€0.7m total value 8 additional projects in negotiation	Contract pipeline and capacity planning
Translational / regulatory / valorisation	1 completed, 5 ongoing 5 under negotiation	Convert discussions into scoped contracts
Manufacturing and quality control	First services from approved laboratories 3 manufacturing opportunities in negotiation	Facility readiness and service contracting

Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

KEY MESSAGES – LESSONS LEARNED

What the CREATIC experience teaches us about building sustainable Centres of Excellence



Financováno Evropskou unií
Ministerstvo školství, mládeže a tělovýchovy

MUNI | CREATIC

Central European Advanced
Therapy and Immunotherapy Centre



**Funded by
the European Union**

MUNI
MED



Ministry of Education,
Youth and Sports
of the Czech Republic

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Research Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.