Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	sukls256794/2022
2. Name of authorisation holder	SCT Cell Manufacturing s.r.o. (ORG-100043443 / LOC-100071862)
3. Address(es) of manufacturing site(s)	SCT Cell Manufacturing s.r.o. (ORG-100043443 / LOC-100071862), Jankovcova 1518/2, Holesovice, Prague 7, 170 00, Czechia
4. Legally registered address of authorisation holder	Jankovcova 1518/2, Holesovice, Prague 7, 170 00, Czechia
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2022-12-05
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3(Addresses of Contract Manufacturing Site(s)) Annex 4(Addresses of Contract laboratories) Annex 5(Name of Qualified Person) Annex 6(Name of responsible persons) Annex 7(Date of inspection on which authorisation granted, scope of last inspection) Annex 8(Manufactured/ imported products authorised)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3] *The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : SCT Cell Manufacturing s.r.o., Jankovcova 1518/2, Holesovice, Prague 7, 170 00, Czechia

Additional Details:

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 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 (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.3 Cell therapy products 1.3.1.4 Gene therapy products
	1.3.2 Batch Certification (list of product types) 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility 1.6.3 Chemical/Physical 1.6.4 Biological
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared

	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation 2.3.2 Importation of intermediate which undergoes further processing

Any restrictions or clarifying remarks related to the scope of these Importation operations (for Public users)

2.1.3 Chemical/Physical: Physical only 2.3.2 Importation of intermediate which undergoes further processing: Small volume liquid medicinal products (liquid and frozen), lyophilisates