

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 17328
2: Name of authorisation holder	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN, 20 GUILFORD STREET, LONDON, WC1N 1DZ, UNITED KINGDOM
4: Legally registered address of authorisation holder	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, GENE AND CELL THERAPY, GREAT ORMOND STREET, LONDON, WC1N 3JH, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	16/10/2023
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN**, 20 GUILFORD STREET, LONDON, WC1N 1DZ, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 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 investigational medicinal products**
  - [ 1.3.1 ] Biological medicinal products
    - [ 1.3.1.3 ] Cell therapy products
    - [ 1.3.1.4 ] Gene therapy products
  - Special Requirements**
    - Viral vectors
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.3 ] Cell therapy products
  - [ 1.3.2.4 ] Gene therapy products
- Special Requirements**
  - Viral vectors
- [ 1.4 ] Other investigational medicinal products or manufacturing activity**
  - [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:
    - [ 1.4.2.1 ] Filtration
- [ 1.5 ] Packaging**
  - [ 1.5.2 ] Secondary packaging

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST**, GENE AND CELL THERAPY, GREAT ORMOND STREET, LONDON, WC1N 3JH, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> <ul style="list-style-type: none"> <li>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)           <ul style="list-style-type: none"> <li>[ 1.1.1.4 ] Small volume liquids</li> </ul> </li> <li>[ 1.1.3 ] Batch certification</li> </ul> <b>[ 1.3 ] Biological investigational medicinal products</b> <ul style="list-style-type: none"> <li>[ 1.3.1 ] Biological medicinal products           <ul style="list-style-type: none"> <li>[ 1.3.1.3 ] Cell therapy products</li> <li>[ 1.3.1.4 ] Gene therapy products</li> </ul> </li> <li>[ 1.3.2 ] Batch certification           <ul style="list-style-type: none"> <li>[ 1.3.2.3 ] Cell therapy products</li> <li>[ 1.3.2.4 ] Gene therapy products</li> </ul> </li> </ul> <b>[ 1.5 ] Packaging</b> <ul style="list-style-type: none"> <li>[ 1.5.2 ] Secondary packaging</li> </ul>

