Bezirksregierung Koeln

CERTIFICATE NUMBER: ***DE_NW_04_GMP_2022_0011***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
A15-D2001/20/EC

The competent authority of Germany confirms the following:
The manufacturer: ***Universitaetsklinikum Bonn AöR***
Site address: ***Venusberg-Campus 1, Venusberg, Bonn, North Rhine-Westphalia, 53127, Germany***
OMS Organisation Id. / OMS Location Id.: / ***LOC-100052664***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_NW_04_MIA_2022_0010*** in accordance with Art. 13 of Directive 2001/20/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-07-27***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.1 Blood products
	1.3.2 Batch Certification (list of product types) 1.3.2.1 Blood products
1.4	**Other products or manufacturing activity**
	1.4.3 Other: - Human plasma for fractionation from apheresis and/or whole blood - Lymphocyte concentrates from apheresis (also cryopreserved) as starting material for the production of CAR-T cell therapeutics for autologous use(en)
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

The authorisation includes only the premises of the Institute for Experimental Hematology and Transfusion Medicine (IHT) of the University Hospital Bonn, Venusberg-Campus 1, Building 43, 53127 Bonn The authorisation refering to 1.3.1.1 includes: - peripheral blood stem cells - allogeneic blood preparations cryopreserved - other products - allogeneic blood preparations Donor lymphocyte concentrates from apheresis cryopreserved - peripheral blood stem cells - autologous blood preparations cryopreserved - other products - autologous blood preparation Serum eye drops from whole blood cryopreserved

2022-04-05

Name and signature of the authorised person of the Competent Authority of

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Confidential
Bezirksregierung Köln
Tel:***Confidential***
Fax:***Confidential***