Change Notification
CC-21-0276

Change of regulatory disclaimer of lentiviral vectors

<table>
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<th>Product</th>
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<tr>
<td>Lentiviral Vector aCD19 CAR SF</td>
<td>200-072-102</td>
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<td>Lentiviral Vector aCD20-CD19 Tandem CAR</td>
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<td>Lentiviral Vector aCD22-CD19 CAR</td>
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<td>Lentiviral Vector aCD22-CD19 CAR</td>
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Category of change: Change of regulatory disclaimer

Current State: The following disclaimer is written on the Certificate of Analysis (CoA) of lentiviral vector products:

“Lentiviral vector products are for research use or for manufacturing of Investigational Medicinal Products (IMPs), as indicated on the label. Lentiviral vector products are for ex vivo cell culture processing only and are not intended for direct in vivo human application. Lentiviral vector products are manufactured and tested under a quality system certified to ISO 13485 (Germany) and in compliance with relevant GMP/cGMP guidelines 21 CFR 210 and 211 (USA). Miltenyi Biotec GmbH (Germany) holds a manufacturing and/or import license for dedicated Lentiviral vector products of different specificity indicated for manufacturing of IMPs. For existing permissions and regulatory status in the USA, please contact Lentigen Technology Inc.

Miltenyi Biotec as the manufacturer of the Lentiviral vector products does not give any recommendations regarding the use of the transduced cells for therapeutic purposes and does not make any claims regarding a clinical benefit. For the manufacturing and use of transduced cells in humans the national legislation and regulations must be followed. In the EU the specific regulation is 1394/2007, while in the US it is 21CFR part 1271. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a Lentiviral vector product.”

Planned change: For lentiviral vectors produced in Teterow the following disclaimer will be written on the CoA/Product quality certificate:

“Lentiviral vector products are for ex vivo cell processing only and are not intended for direct in vivo human application. Lentiviral vector products are manufactured and tested in compliance with relevant GMP/cGMP guidelines. Miltenyi Biotec (Germany) holds a manufacturing and import license for specific Lentiviral vector products. For existing permissions and regulatory status in the USA, please contact Lentigen Technology Inc.”
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Miltenyi Biotec as the manufacturer of the Lentiviral vector products does not give any recommendations regarding the use of the transduced cells for therapeutic purposes and does not make any claims regarding a clinical benefit. For the manufacturing and use of transduced cells in humans the national legislation and regulations must be followed (in the EU the specific regulation is C(2017) 7694 Good Manufacturing Practice for Advanced Therapy Medicinal Products). Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a Lentiviral vector product.”

Justification/Evaluation: The regulatory disclaimer will be adapted to give more details on the quality system under which the lentiviral vectors are produced.

There is no change of raw material or manufacturing process. Therefore no impact on the performance, quality and safety of the affected product could be identified.

Estimated Implementation Q4/2021

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.


Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG