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Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
29 December 2016

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(54) Title: DRY POWDER COMPOSITION COMPRISING LONG-CHAIN RNA

(57) Abstract: The present invention is directed to a storage-stable formulation of long-chain RNA. In particular, the invention concerns a dry powder composition comprising a long-chain RNA molecule. The present invention is furthermore directed to methods for preparing a dry powder composition comprising a long-chain RNA molecule by spray-freeze drying. The invention further concerns the use of such a dry powder composition comprising a long- chain RNA molecule in the preparation of pharmaceutical compositions and vaccines, to a method of treating or preventing a disorder or a disease, to first and second medical uses of such a dry powder composition comprising a long-chain RNA molecule and to kits, particularly to kits of parts, comprising such a dry powder composition comprising a long-chain RNA molecule.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/000843

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K48/00 C12N15/10
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, BIOSIS, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/069528 A1 (CUREVAC GMBH [DE]; MUTZKE THORSTEN [DE]; KETTERER THOMAS [DE]; VON DER) 16 June 2011 (2011-06-16) claims 1, 8 page 41, lines 39-44 page 52, lines 4-8 page 60, line 31 - page 61, line 6 -----	1-14, 24-36
X	WO 2011/069529 A1 (CUREVAC GMBH [DE]; MUTZKE THORSTEN [DE]) 16 June 2011 (2011-06-16) claim 12 -----	1-14, 24-36
X	US 2007/172430 A1 (BRITO LUIS [US] ET AL) 26 July 2007 (2007-07-26) claims 1, 8 paragraph [0054] paragraphs [0020], [0022] -----	1-36
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 2016	15/11/2016

Name and mailing address of the ISA/	Authorized officer
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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JENSEN D M K ET AL: "Spray drying of siRNA-containing PLGA nanoparticles intended for inhalation", JOURNAL OF CONTROLLED RELEASE, ELSEVIER, AMSTERDAM, NL, vol. 142, no. 1, 25 February 2010 (2010-02-25), pages 138-145, XP026892483, ISSN: 0168-3659, DOI: 10.1016/J.JCONREL.2009.10.010 [retrieved on 2009-10-22] cited in the application abstract title -----	1-36

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2016/000843

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14(completely); 24-36(partially)

   Dry powder composition comprising a long-chain RNA molecule, and subject-matter relating thereto.

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2. claims: 15-23(completely); 24-36(partially)

   Method for preparing a dry powder comprising a long-chain RNA molecule, wherein the method comprises the following steps:
   a) providing a liquid comprising the long-chain RNA molecule,
   b) drying the liquid provided in step a) by spray-freeze drying,
   and subject-matter relating thereto.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/000843

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011069528 A1	16-06-2011	WO 2011069528 A1	16-06-2011
		WO 2011069587 A1	16-06-2011
WO 2011069529 A1	16-06-2011	US 2012258046 A1	11-10-2012
		US 2015141498 A1	21-05-2015
		WO 2011069529 A1	16-06-2011
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US 2007172430 A1	26-07-2007	US 2007172430 A1	26-07-2007
		US 2011077284 A1	31-03-2011