



## (51) International Patent Classification:

A61K 9/133 (2006.01) A61K 9/127 (2006.01)  
A61K 39/145 (2006.01) A61K 39/00 (2006.01)  
A61K 39/12 (2006.01)

## (21) International Application Number:

PCT/EP2014/078463

## (22) International Filing Date:

18 December 2014 (18.12.2014)

## (25) Filing Language:

English

## (26) Publication Language:

English

## (30) Priority Data:

13198296.9 19 December 2013 (19.12.2013) EP

(71) Applicant: **CRUCELL HOLLAND B.V.** [NL/NL];  
Archimedesweg 4, NL-2333 CN Leiden (NL).

(72) Inventors: **ADRIAANSEN, Janik**; Archimedesweg 4-6,  
NL-2333 CN Leiden (NL). **DORO, Francesco**;  
Archimedesweg 4-6, NL-2333 CN Leiden (NL).

(74) Agents: **BESLIER, Victor** et al.; Archimedesweg 4-6,  
NL-2333 CN Leiden (NL).

(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,  
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,  
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,  
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,  
KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG,  
MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM,  
PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC,  
SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,  
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,  
TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU,  
TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE,  
DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,  
LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,  
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,  
GW, KM, ML, MR, NE, SN, TD, TG).

## Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

[Continued on next page]

(54) Title: IMPROVED FORMULATIONS FOR VIROSOMES

&lt;-65°C 12 W      Trivalent - A/California

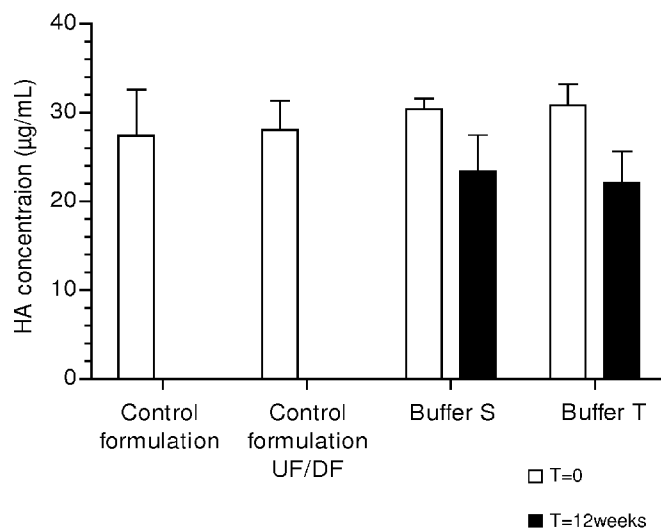


Fig. 17D

(57) Abstract: The present invention provides virosome formulations, in particular liquid pharmaceutical formulations comprising virosomes. A preferred embodiment is a composition comprising: a) virosomes; b) a KH2 P04 /Na2 HP04 buffer, wherein the phosphate concentration is ranging between about 15 mM and 30 mM; c) a salt, wherein the salt concentration is higher than 60 mM; d) a disaccharide, wherein said composition has a pH ranging between 6.5 and 8. Also disclosed is a method of preserving virosomes preparing the just defined composition.

**Published:****(88) Date of publication of the international search report:**

27 August 2015

- *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))*