

**THE NATIONAL INSTITUTES OF HEALTH
BIOLOGICAL MATERIALS LICENSE AGREEMENT**

This **Agreement** is entered into between the National Institutes of Health (“**NIH**”) within the Department of Health and Human Services (“**HHS**”) through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and Hookipa Biotech AG (“**Licensee**”), a corporation of Vienna, Austria, having an office at Helmut-Qualtinger-Gasse 2, 1030 Vienna, Austria.

1. Definitions:

- (a) “**BLA**” refers to a biologics license application filed with the **FDA** (or an equivalent application filed with another regulatory body).
- (b) “**Clinical Trial**”, for the purposes of this **Agreement**, includes clinical trials investigating products derived from clinical trial materials manufactured from the **Master** and **Working Cell Banks** derived from **VRC’s Research Cell Bank** as well as clinical trials for products derived from clinical trial materials manufactured using third party cell banks, provided **Virus Seeds** manufactured from the **Master** and/or **Working Cell Banks** derived from **VRC’s Research Cell Banks** were used in such third party cell banks.
- (c) “**CMO**” means a Contract Manufacturing Organization under contract to the **Licensee** for the purpose of outsourcing pharmaceutical manufacturing.
- (d) “**Government**” means the government of the United States of America.
- (e) “**FDA**” means the Food and Drug Administration.
- (f) “[***] cells” [***].
- (g) “**IND**” refers to an investigational new drug submission filed with the **FDA** (or an equivalent application filed with another regulatory body).
- (h) “**Licensed Field of Use**” means manufacturing of **Master Cell Banks** and **Working Cell Banks** that will subsequently be used to manufacture **Virus Seeds** and **Clinical Trial** materials and/or commercial materials of **Vaccine** vectors based on arenavirus vectors including recombinant lymphocytic choriomeningitis virus (LCMV). **Master Cell Banks** and **Working Cell Banks, Virus Seeds** and **Vaccine** lots may be manufactured by **Licensee** or by **CMOs**.
- (i) “**Licensed Products**” means **Materials** and all progeny, subclones, and unmodified derivatives of the cell clones.
- (j) “**LCMV-GP [***] cells**” means cells produced by transfecting **VRC-[***] cells** with a gene for the glycoprotein (“**GP**”) of lymphocytic choriomeningitis virus (“**LCMV**”), including [***] that stably expresses LCMV-GP on the cell surface, [***].
- (k) “**Master Cell Bank**” means a good manufacturing practices (GMP) manufactured culture of well characterized cells derived from **VRC’s Research Cell Bank**, adapted to a suitable medium composition and distributed into containers in a single operation, processed together in such a manner as to ensure uniformity and stored in such a manner as to ensure stability.
- (l) “**Materials**” means the following biological materials developed at the

VRC:

(i) **VRC's Research Cell Bank**; three (3) x two (2) ml vials of frozen cells of [***];

(ii) Technical Reports, which are to be treated as confidential even if not every page might be marked as such, include the following information:

1. Specification of the parental **VRC-[***] cells** used to derive the **LCMV-GP [***] cells** and the [***] cell clone;

2. Materials (including source and lot numbers) and methods used to derive the [***] cell clone;

3. Results of characterization of the [***] cell clone, including expression of GP;

4. Preparation of and cryopreservation of the **VRC's Research Cell Bank**;

5. Results of the limited tests performed on the **VRC's Research Cell Bank**; and

6. Description of the equipment and facilities used in deriving and banking the [***] cell clone and **VRC's Research Cell Bank**.

(iii) A copy of the **VRC [***] cells Master File**; and

(iv) A letter to **CBER/FDA** to be submitted by the **VRC** permitting **Licensee** to cross-reference the **VRC-[***] cells Master File**. A copy of said letter shall be provided to **Licensee**.

(m) “**MTA**” means a Material Transfer Agreement (**NIAID** ref.# 2012-2935) signed between **NIAID**, AdVec, Inc. and **Licensee** with an effective date of December 19, 2012, for the transfer to **Licensee** of **VRC-[***] cells**, uncloned **LCMV-GP [***] cells** and cloned [***] cell clones for internal research use by **Licensee**.

(n) “**NIAID**” means the National Institute of Allergy and Infectious Diseases, a component of **NIH**

(o) “**Vaccine**” means a viral vector produced in the **Master Cell Bank** or **Working Cell Bank** or a third party cell bank and used for preclinical and/or clinical testing.

(p) “**Virus Seed**” means a viral vector stock produced in a cell bank, such as the **Master Cell Bank** or **Working Cell Bank**, that is subsequently used to inoculate said **Master Cell Bank** and/or **Working Cell Bank** or a third party cell bank for the purpose of producing **Vaccine** batches.

(q) “**VRC**” means the Vaccine Research Center, a component of **NIAID**.

(r) “**VRC-[***] cells**” means a cGMP qualified master cell bank of modified [***] cells produced at the **VRC**. The **VRC-[***] cells** have been adapted at the **VRC** to grow in suspension culture in serum free medium and therefore have notable morphological differences from the original adherent [***] cells as described in [***].

(s) “**VRC-[***] cells Master File**” means the master file for the master cell

bank and a working cell bank of the parental **VRC-[***] cells bank [***]** used to produce the **VRC's Research Cell Bank of LCMV-GP [***] cells clone [***]**.

(t) **"VRC's Research Cell Bank"** means a research cell bank of [***], a clone of **LCMV-GP [***] cells** isolated by the **VRC**

(u) **"Working Cell Bank"** means a culture of cells derived from the **Master Cell Bank** and intended for use in the preparation of cell cultures used for production of **Virus Seeds** and/or **Vaccines**.

2. The **Licensee** desires to obtain a license from the **NIH** to use the **Licensed Products** provided under this **Agreement** in its commercial research or product development and marketing activities. The **Licensee** represents that it has the facilities, personnel, and expertise to use the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Licensed Products** for commercial use or commercial research.

3. The **NIH** hereby grants to the **Licensee** a worldwide, non-exclusive license to make, have made, import and use the **Licensed Products** in the **Licensed Field of Use**. The **Licensee** can transfer the **Licensed Products** to **CMOs** only for use in relation to services provided to **Licensee** in accordance with the **Licensed Field of Use**.

4. Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld, the **Licensee** may enter into sublicensing agreements for the rights granted under this **Agreement** to third parties who have entered an agreement with the **Licensee** to develop and commercialize a **Vaccine** based on the **Licensee's** proprietary Vaxwave® technology, provided that:

(a) The **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **NIH** of Paragraphs 15-17, 21 and 23 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements;

(b) Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Paragraph 18. This conversion is subject to **NIH** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**; and

(c) The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within [***] of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

5. The **NIH** agrees to allow the **Licensee** to use **Virus Seeds** and **Vaccines**, manufactured from the **Master Cell Banks** and/or **Working Cell Banks**, in third party cell bank(s) to manufacture **Clinical Trial** material and/or commercial materials of **Vaccines** under **Licensee's** own discretion. In such situation(s), the **NIH** agrees to allow the **Licensee** to cross-reference the **VRC-[***] cells Master File** for any **IND** or **BLA** for any products derived from such **Virus Seeds**, provided that such **Clinical Trial** materials and/or commercial materials were manufactured using such **Virus Seeds** in such third party's cell bank. Such continued use of the **Virus Seeds** and cross-referencing of the **VRC-[***] cells Master File** shall be subject to the reduced minimum annual royalty payments set forth in Paragraph 8, provided that the **Licensee** notifies the **NIH** in advance of its intent to use **Virus Seeds** manufactured from the **Master Cell Banks** and/or **Working Cell Banks** derived from **VRC's Research Cell Banks** in a third party's cell banks.

6. The **Licensee** agrees that the **MTA** will be terminated on the effective date of this **Agreement**. **Licensee** further agrees to provide the **NIH** with written certification of the destruction of

VRC-***] cells, uncloned LCMV-GP ***] cells and cloned ***] cell clones

7. The **Licensee** agrees that the **Licensee** is solely responsible for obtaining and maintaining any required license from ***] for the background rights for the commercial use of the ***] cells.

8. In consideration of the license granted herein, and subject to the termination provisions set forth herein, the **Licensee** hereby agrees to make the following payments to the **NIH**. As contemplated by paragraph 5, where the **Virus Seeds** and/or **Vaccines** are manufactured in one or more third party cell banks, and wherein the **Licensee** is required to make royalty payments to said one or more third parties, the payments to the **NIH** listed below shall be reduced by an amount equal to said royalty payments to said one or more third parties, provided that payments to the **NIH** shall not be reduced by more than ***] of the following payments:

(a) Within ***] of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of ***]

(b) Minimum annual royalty payments as following:

(i) ***] for the years prior to filing an **IND** with the **FDA** or foreign equivalent are due and payable on January 1 of each calendar year. The first minimum annual royalty is due and payable on January 1, 2014; or

(ii) ***] are due and payable on January each calendar year following the filing of an **IND** with the **FDA** or foreign equivalent and prior to dosing of first patient in first Phase I **Clinical Trial**; or

(iii) ***] are due and payable on January 1 of each calendar year following the dosing of first patient in first Phase I **Clinical Trial** and prior to dosing of first patient in first Phase II **Clinical Trial**; or

(iv) ***] are due and payable on January 1 of each calendar year following the dosing of first patient in first Phase II **Clinical Trial** and prior to dosing of first patient in first Phase III **Clinical Trial**; or

(v) ***] are due and payable on January 1 of each calendar year following the dosing of first patient in first Phase III **Clinical Trial** and prior to acceptance of **BLA** in the US or foreign equivalent; or

(vi) ***] are due and payable on January 1 of each calendar year following acceptance of **BLA** in the US or foreign equivalent and prior to marketing approval in the US or first foreign market; or

(vii) ***] are due and payable on January 1 of each calendar year following marketing approval in the US or first foreign market.

(c) The **Licensee** agrees to pay the **NIH** additional sublicensing royalties of ***] on the fair market value of any consideration received for granting each sublicense within ***] of the execution of each sublicense.

(d) All payments required under this **Agreement** shall be paid in U.S. dollars and payment options are listed in Appendix B. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

(i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**; and

(ii) Additional royalties may be assessed by the **NIH** on any payment that is more than [***] overdue at the rate of [***] per month. This [***] per month rate may be applied retroactively from the original due date until the date of receipt by the **NIH** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIH** from exercising any other rights it may have as a consequence of the lateness of any payment.

9. Upon receipt by the **NIH** of the license issue royalty and verification of this royalty, the **NIH** agrees to provide the **Licensee** with the **Materials**, and to replace these **Materials**, as available, at reasonable cost, in the event of their unintentional destruction. The **NIH** shall provide the **Materials** to the **Licensee** at the **Licensee's** expense and as specified in Appendix A.

10. The **Licensee** agrees to make written reports to the **NIH** within [***] of December 31 for each calendar year. This report shall state the number and description of **Licensed Products** made or otherwise disposed of. The **Licensee** shall submit each report to the **NIH** at the Mailing Address for **Agreement** notices indicated on the Signature Page.

11. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 27 are not fulfilled, and shall expire twenty (20) years from this effective date, unless previously terminated under the terms of Paragraphs 18 or 19. **Licensee** shall have the option of extending the term of the **Agreement** by an additional 1 (one) year period. [***] prior to the expiry of the initial 20 year term or a 1 (one) year extended term, the **Licensee** notify **NIH** that it will be exercising its option to extend the **Agreement** by an additional year.

12. The **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of the **NIH** except as provided in Paragraphs 3 and 4.

13. This **Agreement** does not preclude the **NIH** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes. For the avoidance of doubt, the **NIH** shall not be allowed to distribute **Vaccines, Virus Seeds, Master Cell Bank** and/or **Working Cell Bank** generated by or on behalf of the **Licensee**.

14. By this **Agreement**, the **NIH** grants no patent rights expressly or by implication to any anticipated or pending **NIH** or **FDA** patent applications or issued patents.

15. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO THE **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. The **Licensee** accepts license rights to the **Materials** and the **Licensed Products** "as is", and the **NIH** does not offer any guarantee of any kind.

16. The **Licensee** agrees to indemnify and hold harmless the **Government** from any claims, costs, damages, or losses that may arise from or through the **Licensee's** use of the **Materials** or the **Licensed Products**. The **Licensee** further agrees that it shall not by its action bring the **Government** into any lawsuit involving the **Materials** or the **Licensed Products**.

17. The **Licensee** agrees in its use of the **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national

control authorities. Written notification to the **NIH** of research involving human subjects or clinical trials outside of the United States shall be given no later than [***] prior to commencement of such research or trials.

18. The **Licensee** may terminate this **Agreement** upon [***] written notice to the **NIH** but only after [***] from the effective date of this **Agreement**.

19. The **NIH** may terminate this **Agreement** if the **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within [***] after the date of written notice by the **NIH** of the default.

20. Within [***] of the termination or expiration of this **Agreement**, the **Licensee** agrees to return all **Materials** and the **Licensed Products** to the **NIH**, or provide the **NIH** with written certification of their destruction.

21. Within [***] of termination or expiration of this **Agreement**, the **Licensee** agrees to submit a final report to the **NIH**, and to submit to the **NIH** a final payment of any royalties due. The **Licensee** may not be granted additional **NIH** licenses if this final reporting requirement is not fulfilled.

22. The **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the

Materials or the **Licensed Products**, the **Licensee** shall acknowledge the contribution of [***], at the **NIH** supplying the **Materials**, unless requested otherwise by the **NIH**.

23. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. The **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

24. This **Agreement** constitutes the entire understanding of the **NIH** and the **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials** or the **Licensed Products**.

25. The provisions of this **Agreement** are severable, and in the event that any provision of the **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

26. Paragraphs 8, 15, 16, 20-22 and 26 of this **Agreement** shall survive termination or expiration of this **Agreement**.

27. The terms and conditions of this **Agreement** shall, at the **NIH**'s sole option, be considered by the **NIH** to be withdrawn from the **Licensee**'s consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within [***] from the date of the **NIH** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

THE NIH BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

LEGAL ADDRESSES AND BANKING DETAILS OF THE PARTIES

_____	_____
_____	_____
_____	_____
_____	_____
