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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Metarrestin and its Analogs for the Treatment of Metastatic Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Oncala Bio Inc. ("Oncala Bio"), headquartered in Bend, OR**.**

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences' Office of Strategic Alliances on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: (301)-642-0460; E-mail: sury.vepa@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S Provisional Patent Application No. 61/576,780 filed on 12/16/2011 which is entitled "Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-276-2011-0-US-01);

2. International Patent Application No. PCT/US2012/070155 filed on 12/17/2012 which is entitled “Compounds and Methods for The Prevention and Treatment of Tumor Metastasis and Tumorigenesis” (HHS Ref. No. E-276-2011-0-PCT-02);
3. Australian Patent Application No. 2012353651 filed on 12/17/2012 which is entitled “Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis” which was issued as Patent No. 2012353651 on 03/29/2018(HHS Ref. No. E-276-2011-0-AU-03);
4. Australian Patent Application No. 2017276258 filed on 12/17/2012 which is entitled “Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis” which was issued as Patent No. 201727658 on 01/16/2020 (HHS Ref. No. E-276-2011-0-AU-10);
5. Canadian Patent Application No. 2859370 filed on 12/17/2012 which is entitled “Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis” which was issued as Patent No. 2859370 on 01/26/2021(HHS Ref. No. E-276-2011-0-CA-04);
6. European Patent Application No. 12806846.7 filed on 12/17/2012 which is entitled “Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis” which was issued as Patent No. 2791142 on 07/03/2019 and validated in Germany, Spain, France, Great Britain, Italy and Turkey (HHS Ref. No. E-276-2011-0-EP-05);
7. US Patent Application No. 14/364,759 filed on 06/12/2014 which is entitled “Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis” which was issued as Patent No. 9,663,521 on 05/30/2017 (HHS Ref. No. E-276-2011-0-US-07);
8. US Patent Application No. 15/606,740 filed on 05/26/2017 which is entitled “Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and

Tumorigenesis" which was issued as Patent No. 10,301,314 on 05/28/2019 (HHS Ref. No. E-276-2011-0-US-08);

9. Japanese Patent Application No. 547550/2014 filed on 06/13/2014 which is entitled "Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" which was issued as Patent No. 6463130 on 01/01/2019 (HHS Ref. No. E-276-2011-0-JP-06);
10. Japanese Patent Application No. 102107/2017 filed on 05/23/2017 which is entitled "Compounds and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" which was issued as Patent No. 6726640 on 07/01/2020 (HHS Ref. No. E-276-2011-0-JP-09);
11. U.S Provisional Patent Application No. 62/671,964 filed on 05/15/2018 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-US-01);
12. International Patent Application No. PCT/US2019/32461 filed on 05/15/2019 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-PCT-02);
13. Canadian Patent Application No. 3100211 filed on 11/12/2020 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-CA-03);
14. Australian Patent Application No. 2019271208 filed on 11/13/2020 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-AU-04);
15. Japanese Patent Application No. 2020-564095 filed on 11/13/2020 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-JP-06);

16. U.S. Patent Application No. 17/055,256 filed on 11/13/2020 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-US-07); and
17. European Patent Application No. 19728226.2 filed on 12/09/2020 which is entitled "Formulations and Methods for the Prevention and Treatment of Tumor Metastasis and Tumorigenesis" (HHS Ref. No. E-114-2018-0-EP-05).

The patent rights in these inventions have been either assigned and/or exclusively licensed to the government of the United States of America, University of Kansas and Northwestern University.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

"Development, manufacture, use and commercialization of Metarrestin and its analogs disclosed and claimed in the prospective licensed patent rights, for the treatment of perinucleolar compartment (PNC) positive cancers or metastatic cancers."

E-276-2011 and E-104-2018 patent families are primarily directed to novel compositions, methods and formulations, which are selective against metastasis across different preclinical cancer histologies and without appreciable toxicity. Among others, the subject patent families disclose or claim the use of the small molecule metarrestin for the treatment of several types of metastatic cancers by disrupting a subcellular structure called the perinucleolar compartment (PNC) which is frequently found in metastatic tumors and cancer stem cells.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Center for Advancing Translational Sciences receives written evidence and

argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

March 21, 2023.

Joni L. Rutter,

Director,

Office of the Director,

National Center for Advancing Translational Sciences.

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