**Billing Code 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive Patent License: Treatment of Hermansky-Pudlak Syndrome and Idiopathic Pulmonary Fibrosis**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung and Blood Institute (NHLBI) and the National Human Genome Research Institute (NHGRI), both of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an exclusive patent license to Inversago Pharma Inc., located in Montreal, Quebec, Canada, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the National Human Genome Research Institute's Technology Transfer Office 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: Anna Solowiej, Ph.D., J.D., Senior Licensing and Patenting Manager, NHGRI Technology Transfer Office; Telephone (301)435-7791; E-mail: anna.solowiej@nih.gov.

**SUPPLEMENTARY INFORMATION:**

The following and all continuing U.S. and foreign patents/patent applications thereof are the

intellectual properties to be licensed under the prospective agreement to Inversago Pharma Inc.:

| NIH REF NO. | PATENT No. or APPLICATION No. | ISSUE DATE | FILING DATE | TITLE |
|---|---|---|---|---|
| E-282-2012-0-US-01 | 61/725,949 | | November 13, 2012 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-PCT-02 | PCT/US2013/069686 | | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-US-03 | 9,765,031 | September 19, 2017 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-CA-04 | 2889697 | | April 27, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-EP-05 | 13802153.0 | TBD | June 01, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-CH-12 | 13802153.0 | TBD | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-DE-13 | 13802153.0 | TBD | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-FR-14 | 13802153.0 | TBD | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-GB-15 | 13802153.0 | TBD | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-IE-16 | 13802153.0 | TBD | November 12, 2013 | Cannabinoid Receptor Mediating Compounds |

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| E-282-2012-0-IN-06 | 3733/DELNP/2015 | | May 1, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-JP-07 | 6272626 | January 12, 2018 | May 11, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-CN-08 | ZL201380069389.9 | August 20, 2019 | July 3, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-US-09 | 10,683,270 | June 16, 2020 | August 10, 2017 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-US-10 | 15/674,333 | TBD (application allowed) | August 10, 2017 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-0-US-11 | 16/870,093 | | May 8, 2020 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-1-US-01 | 62/171,179 | | June 4, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-1-PCT-02 | PCT/US2016/035291 | | June 1, 2016 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-1-EP-05 | 16728547.7 | | June 1, 2016 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-1-US-08 | 15/579,123 | | December 1, 2017 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-1-US-09 | 16/438,850 | | June 12, 2019 | Cannabinoid Receptor Mediating Compounds |

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| E-282-2012-2-US-01 | 15/061,829 | | March 4, 2016 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-2-PCT-02 | PCT/US2017/020250 | | March 1, 2017 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-2-CN-03 | 2017800118698 | | March 1, 2017 | Cannabinoid Receptor Mediating Compounds |
| E-282-2012-2-EP-04 | 17711443.6 | | March 1, 2017 | Cannabinoid Receptor Mediating Compounds |
| **NIH REF NO.** | **PATENT No. or APPLICATION No.** | **ISSUE DATE** | **FILING DATE** | **TITLE** |
| E-140-2014-0-US-01 | 61/991,333 | | May 9, 2014 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-PCT-02 | PCT/US2015/029946 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-AU-03 | 2015255765 | | November 7, 2016 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-CA-04 | 2948349 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-CN-05 | 201580028788.X | February 7, 2020 | May 8, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-EP-06 | 15728668.3 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds |

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| E-140-2014-0-IN-07 | 201637038171 | | November 8, 2016 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-JP-08 | 2017-511558 | TBD (application allowed) | May 8, 2015 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-US-09 | 10,329,259 | June 25, 2019 | November 8, 2016 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-HK-10 | 17105705.6 | | June 9, 2017 | Cannabinoid Receptor Mediating Compounds |
| E-140-2014-0-AU-11 | 2019227889 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds |

The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent license territory may be worldwide and a field of use limited to human therapeutics for Hermansky-Pudlak syndrome and idiopathic pulmonary fibrosis.

The invention covered by the patents and patent applications pertaining to HHS Ref. No. E-282-2012 relates to cannabinoid receptor 1 ($CB_1R$) inverse agonists. $CB_1R$ activation plays a key role in appetitive behavior, metabolism, and tissue fibrosis. Of importance as a therapeutic target here is that the receptor is expressed in both peripheral tissue as well as the central nervous system.

The invention is a class of pyrazole compounds that act as CB1 receptor inverse agonists and have been shown effective at reducing obesity and its associated metabolic consequences while having no experimentally discernable neuropsychotropic side effects that are considered adverse, unlike the earlier antagonists rimonabant. These $CB_1R$ receptor compounds were developed

with the goals of limiting their brain penetrance without losing their metabolic efficacy due to CB1 inverse agonism, and having a primary metabolite directly targeting enzymes involved in inflammatory and fibrotic processes associated with metabolic and other disorders. The patents are both compositions of matter and methods of use.

The inventions covered by HHS Ref. E-140-2014-0 also pertain to pyrazole $CB_1R$ receptor inverse agonists. In addition, some of these compounds also have a direct inhibitory effect on inducible nitric oxide synthase (iNOS), whereas another group of the compounds directly activates AMP kinase. There is evidence that the metabolic effects of endocannabinoids are mediated by CB1 receptors in peripheral tissues. These dual-target compounds may be useful for treating metabolic disease and related conditions such as obesity and diabetes and their complications, including various forms of tissue fibrosis, without the dangerous side effects.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, NHGRI 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: November 2, 2020

**Claire T. Driscoll,**

*Director,*

*Technology Transfer Office,*

*National Human Genome Research Institute.*

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