EX-10.4 5 ex10-4.htm

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EXHIBIT 10.4

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT ("Agreement"), made as of the date of last signature ("Effective Date"), by and between **ROSWELL PARK CANCER INSTITUTE CORPORATION D/B/A ROSWELL PARK COMPREHENSIVE CANCER CENTER** ("**Institution**"), a New York State public benefit corporation, with its principal office located at Elm and Carlton Streets, Buffalo, NY 14263, employer of, Brahm Segal, MD ("Principal Investigator"), and **AIM ImmunoTech Inc.** (hereinafter "**AIM**"), a corporation with its principal place of business at 2117 SW Highway 484, Ocala, Florida 34473. The Institution and AIM together are referred to herein as the Parties.

WITNESSETH:

WHEREAS, institution is conducting a clinical Study ("Study") to "Phase 1b Trial of Rintatolimod and IFNα Regimen in Cancer Patients with Mild or Moderate COVID-19 infection;" and

WHEREAS, AIM is providing Rintatolimod, also known as Ampligen® ("Study Drug"), information, and funding to Institution as a collaborator and partner of the Study and in support of the Study; and,

WHEREAS, Institution is a National Cancer Institute-designated Comprehensive Cancer Center and conducts clinical research studies designed to test, *inter alia,* methods of preventing cancer and

WHEREAS, AIM is an immuno-pharma company focused on the research and development of therapeutics to treat multiple types of cancer; and

WHEREAS, Institution has reviewed sufficient information regarding the Study Drug and has prepared the Protocol for the Study, and desires to conduct the Study as Study Sponsor.

NOW, THEREFORE, in consideration of the premises and for other good and lawful consideration, receipt of which is acknowledged, the Parties agree as follows:

1. <u>Study Protocol</u>

Institution will conduct the Study in accordance with "***" and any, subsequent amendments thereto, incorporated by reference herein (the **"Protocol").** The Protocol fully details the clinical research activities and responsibilities to be undertaken, pursued, and followed with all due diligence, by Institution. The Protocol will be considered final after it is approved by the Institution's Institutional Review Board or another designated Institutional Review Board ("IRB"). Institution will provide AIM with the final Protocol, which shall be considered Confidential Information pursuant to section 8 of this Agreement before commencement of the Study. Thereafter, the Protocol may be amended only following consultation with AIM and consent of the Institution and subsequent approval by the IRB.

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2. **Conduct of Study**

a. Standards. Institution agrees to conduct the Study in accordance with generally accepted standards of professional medical practice, and in compliance with: (i) applicable standards of good clinical practice ("GCP"), (ii) the Protocol, and (iii) any and all applicable federal, state, and local laws, regulations, and any other relevant professional standards ("Applicable Laws"). Institution may subcontract its responsibilities under this Agreement to subsites ("Subsites"), provided that such Subsite shall be bound by the same or comparable obligations that Institution has agreed to assume in this Agreement for those specific obligations the Subsite agrees to undertake.

b. ClinicalTrial.gov. AIM shall be listed on the clinicaltrial.gov website as a collaborator on this study. In the event, AIM and Institution agree that errant information posted on clinicaltrial.gov website regarding this Study, Institution will submit and request corrections in a timely manner.

c. Conduct of Study. Institution further agrees that in the performance of the Study their employees and agents shall:

i. Obtain from each Study subject a signed consent form ("Informed Consent Form") in accordance with the Protocol and template informed consent form which has been approved by the IRB in accordance with 21 CFR §56, et, seq., or any successor thereto.
ii. Perform the Study with reasonable care, diligence and skill and ensure that personnel participating in the Study are competent and have appropriate professional qualifications, training and experience.
iii. Promptly notify the IRB of any failures to comply with the Protocol (deviation where necessary to eliminate an immediate hazard(s) to Study subjects or from the Protocol arising out of medical necessity for Study subject safety shall not be deemed a failure to adhere to the Protocol),
iv. Maintain complete and accurate records of the status and progress of the Study as required by the Protocol and with sufficient legibility and detail for use by regulatory agencies **("Study Records")**. The Study Records shall include: case report forms; records reflecting the receipt and disposition of the Study Drug, including all dates, quantity and use by Study subjects; Study safety data required by the Protocol; records of Study subject identification; and clinical observations and laboratory tests as required in the Protocol.
v. Institution will notify AIM within two (2) business days of receiving FDA authorization to initiate the Study.
vi. Institution shall notify AIM within two (2) business days of when first treatment of Study Drug is administered and when first combination cohort Study Drug plus IntronA is administered pursuant to the Protocol. However, Institution is obligated to confirm in a confidential communication whether any dose-limiting toxicity was observed in the initial cohort before implementing the combination cohorts. For the avoidance of doubt, such communication shall be treated as Confidential Information, (as defined below) by the Parties

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vii. Ensure that Confidential Information (as defined below) generated by Institution, or its respective employees or agents is accurate, complete, and legible.

viii. Ensure that Principal Investigator is not currently participating, and shall not participate, in any study which by its nature will preclude Principal Investigator from conducting the Study.

ix. Ensure that neither it, nor any of its employees directly involved with the conduct of the Study, including the Principal Investigator, has ever been, or is currently:

- an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application (a "Debarred Individual"), or an employer, employee, or partner of a Debarred Individual; or
- a corporation, partnership, or association that has been debarred by the FDA pursuant to 21 U.S.C. § 33% (a) or (b) from submitting or assisting in the submission of any abbreviated drug application (a "Debarred Entity"), or an employee, partner, shareholder, member, subsidiary, or affiliate of a Debarred Entity; or
- an individual or corporation, partnership, or association that has been barred from participation in a Federal Health Care Program (as defined in 42 U.S.C. § 1320a (7b (f)), as amended from time to time or in any other governmental payment program.

x. Nothing in this agreement shall prevent AIM from conducting other clinical research studies intravenously or otherwise at other institutions and in other countries related to Ampligen for Cancer, or as an early onset Therapy /Prophylaxis or vaccine adjuvant for SARS-CoV-2/COVID 19. For the avoidance of doubt, nothing in this provision shall be construed as allowing AIM to utilize the protocols drafted by and belonging to Roswell Park and its employees.

3. <u>Study Drug</u>

a. AIM will furnish an agreed upon number of vials of Study Drug, approximately *** vials, *** to the Institution pursuant to this Agreement solely for use in the Protocol. ***

b. Institution will store, handle and administer Study Drug under adequately controlled conditions and in accordance with the Protocol, and Study Drug information provided by AIM.

c. Institution will return or destroy Study Drug in accordance with written directions of AIM and with Institution's drug destruction policies. The Study Drug delivered pursuant to this Agreement shall not be sold, distributed or otherwise made available by the Institution to any other party for any other purpose, without the written consent of AIM, which written consent shall not be unreasonably withheld.

d. Institution will not bill any Study subject or any third parties for any service or activity that is funded in accordance with this Agreement or any Study Drug that is supplied by AIM under this Agreement.

e. The Parties acknowledge that the Study Drug is being provided "as is," without any warranties or representations of any sort, express or implied, including without limitation warranties of merchantability and fitness for a particular use. AIM makes no representation and provides no 'warranty that the use of the Study Drug in the Study will not infringe any patent or other proprietary right of third parties.

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4. Privacy Laws

Institution will ensure that any of its employees, including Principal Investigator, and persons performing the Study on the Institution's behalf will comply with all applicable federal and New York state laws and regulations governing privacy and confidentiality of health information, including without limitation, the Health Insurance Portability and Accountability Act of 1996 and implementing regulations ("HIPAA"), as well as confidentiality agreements entered into by the Parties.

5. Adverse Events

a. Adverse Events. Institution will ensure that its personnel comply with notification procedures provided in the Protocol and Applicable Law, including time limits in the reporting of adverse events of pregnancy, serious adverse events including death, unexpected adverse events and severe adverse events determined to be related or possibly related to the Study Drug. Institution shall notify IRB and AIM's Medical Monitor (email at SAE@aimimmuno.com) of any of the above "Adverse Events" on a quarterly basis. Adverse event reporting to AIM shall be completed on a quarterly basis and will be initiated upon the written request of AIM to the Institution's counsel.

b. Reporting by AIM. AIM shall notify Institution promptly and in writing of any information that could affect the safety of Study subjects or their willingness to continue participation, influence the conduct of the Study, or alter the IRB's approval to continue the Study. AIM shall communicate such information to Institution and Principal Investigator that may directly affect the Study subject's safety or medical care for a period of at least two (2) years following the end of the Study. Subject to other terms of this Agreement, Institution, through its Principal Investigator and/or IRB, as appropriate, will inform Study subjects of additional information in accordance with IRB direction.

e. Reporting by Institution: Institution shall notify AIM of adverse events in section 5.a above. In addition, Institution shall provide IND Safety Reports to AIM at the time of report to FDA or as soon as possible thereafter, according to FDA Reporting time frame specified in Protocol. At study completion, Institution will provide final safety data / listing of all adverse events (including but not limited to severity, relationship to each study medication, to the COVID-19, or to baseline co-morbidities, i.e., cancer, and start and stop dates of each event). Adverse events that result in death shall also capture the above information.

6. **Term, Termination, and Replacement of Principal Investigator**

a. Term. This Agreement shall commence on the Effective Date and shall continue until the completion of the Study or such other date as may be agreed to by the Parties ("Term").

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b. Termination Prior to Expiration. This Agreement may be terminated, in whole or in part, by the Parties prior to the expiration of its Term upon written notice, if any of the following conditions occur:

i. By either party, effective upon notice, if authorization and approval to conduct the Study is withdrawn by the FDA or other regulatory authority.
ii. By either party, effective upon notice, if in the reasonable and good faith opinion of Principal Investigator, Institution, and/or AIM the Study should be terminated for safety reasons.
iii. By AIM, effective upon notice, if Principal Investigator or Institution becomes disbarred
iv. Upon written mutual agreement or upon thirty (30) days' notice for uncured breach of this Agreement.

c. Termination of this Agreement shall not affect any rights or obligations of the Parties that occurred prior to termination of this Agreement or rights or remedies of either party available at law or in equity.

d. Replacement of Principal Investigator. In the event Principal Investigator becomes either unwilling or unable to perform the duties required by this Agreement, upon request by AIM, Institution will cooperate, in good faith and expeditiously, to find a replacement. The Institution's cooperation in finding an acceptable replacement does not negate their obligations to perform this Agreement up to the effective date of termination.

7. **Payment**

The Parties acknowledge that Health Research Inc., Roswell Park Division, a New York non-profit corporation, is authorized to manage funds from clinical research, on behalf of Institution, has an office of Elm and Carlton Streets, Buffalo, New York 14263 and is the Institution's payee ("Payee"), In consideration for performance of the Study and as a collaborator of this Study, AIM will provide funding to Institution, through its Payee and will provide Institution $***. Payments to be distributed as follows:

Study: ***

8. **Confidential Information**

a. Definition. "Confidential Information" will mean all information or data provided by one party to another that a reasonable person familiar with the area would recognize as confidential or proprietary information and materials (whether or not patentable) identified in writing as "Confidential." In addition, Confidential Information includes, but is not limited to clinical data expressly required to be collected by the Study Protocol or pursuant to the terms of this Agreement, the Investigational Drug/Device Brochure, Study Records, preclinical data and formulation information, patent applications, audit reports, study reports, formulas and manufacturing processes, provided or made available to either party.

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b. Obligations. Each party shall maintain in strict confidence all of the other party's Confidential Information and not disclose or disseminate to any third party or use for any purpose other than the performance of the Study. Such Confidential Information shall remain the confidential and proprietary property of the disclosing party, and, shall be disclosed only on a need-to-know basis to employees and agents who are bound by confidentiality terms at least as strict as those herein.

c, Non-applicability. The foregoing obligation of non-disclosure shall not apply to Confidential Information to the extent such information:

i. was available in the public domain at the time of disclosure or subsequently becomes publicly available through no fault of the receiving party;

ii. is disclosed to receiving party by a third party entitled to disclose such information not subject to any obligation of confidentiality, as shown by prior written records

iii. is already known to receiving party prior to disclosure hereunder, as shown by prior written records; or
iv. is independently developed by receiving personnel without reliance on Confidential Information, as shown by prior written records

d. Allowable Disclosures. Confidential information may be disclosed to the extent it is required by Applicable Laws to be disclosed to US federal, state, or local authorities and agencies including the Food and Drug Administration ("FDA") or the Securities and Exchange Commission ("SEC"), provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and reasonable advance notice of such request is given to the other party.

e. Equitable Remedies. Parties acknowledge and agree that ally violation of the terms of this Agreement relating to the disclosure or use of Confidential Information may result in irreparable injury and damage to disclosing party not adequately compensable in money damages, and for which disclosing party will have no adequate remedy at law. Nondisclosing party acknowledges and agrees that if those disclosure terms are violated, then disclosing party has a right to seek injunctions, orders, or decrees to protect the Confidential Information.

f. Period of Confidentiality. The obligations of the Parties under this Section 8 shall continue until ten (10) years from the expiration or termination of this Agreement.

g. Recordkeeping. In accordance with Applicable Law, upon completion of the Study or earlier termination of this Agreement pursuant to section 6, all Study Drug and related materials and all Confidential Information that were furnished under this Agreement will be returned, except for record copies which nondisclosing Party is required to retain and a copy maintained to monitor compliance with this Agreement, Neither Party shall be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by their automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its or their standard archiving and back-up procedures.

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9. **Publication**

a, For purposes of this Agreement, Scientific Publication means any scientific publication or medical communication regarding Study results in any form that is intended for disclosure to third parties, including, without limitation, manuscripts, abstracts, posters, slides or other materials used for presentations.

b. Scientific Publications should be published in a timely manner, in accordance with industry standards, and present scientific information in an accurate and balanced way that does not exclude or inappropriately downplay negative safety or health information. Authorship related to Scientific Publications shall be determined in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

c. Institution shall provide and shall require Principal Investigator to provide AIM with a draft of any proposed Scientific Publication at least thirty (30) days prior to submission of such publication for AIM to ascertain whether any patentable subject matter or Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. AIM shall provide a response to Institution within thirty (30) days after receipt of the draft Scientific Publication ("Review Period"). Institution shall delay any proposed Scientific Publication an additional sixty (60) days in addition to the Review Period in the event AIM so requests to enable AIM to secure patent or other proprietary protection ("Delay Period"). Institution agrees to (i) keep the proposed Scientific Publication confidential until expiration of the Review Period and any Delay Period, and (ii) delete Confidential Information (other than the results of the Study generated hereunder) from any Scientific Publication. In the event that Institution and AIM differ in their conclusions or interpretation of data in the Scientific Publication, the Parties shall use good faith efforts to attempt to resolve such differences through appropriate scientific debate, but, subject to the removal of Confidential Information (other than the results of the Study generated hereunder), Institution, as applicable, shall retain control over the final version of the Scientific Publication.
Nothing herein affords AIM editorial rights with respect to Institution's publications.

10. **Intellectual Property**

a. Pre-existing Property. Institution understands and acknowledges that the Study Drug, Ampligen® (rintatolimod) is the property of AIM and/or that it may be subject to certain intellectual property rights owned by or licensed to AIM including patents, patent applications that may issue as patents in the future, trademarks and trademark applications. All rights to Ampligen® (rintatolimod) belong to AIM. This Agreement shall not be deemed or construed to convey, transfer, or license any of such intellectual property rights to Institution, other than the limited rights necessary to permit Institution to conduct the Study during the term of this Agreement, Further, all intellectual property belonging to either party prior to the execution of this Agreement ("Pre-existing Property") shall remain the separate property of that party and nothing contained in this Agreement shall be deemed to grant either directly or by implication, estoppel or otherwise any license under any patents, patent applications, trademarks, trade secrets, or other proprietary interests to Pre-existing Property of the other party.

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b. New Inventions. Ownership and rights to any new and patentable or unpatentable discovery, technology, know-how or other intellectual property arising from the performance of the Protocol (hereinafter "Other Inventions") shall be determined by the application of U.S. patent laws.

11. **Audits and Inspections**

a. Institution shall notify AIM, or if instructed, its representative, promptly if the FDA or other duly authorized authority requests permission to or does inspect Institution's facilities or research records during the term of this Agreement. Institution will make reasonable efforts to ensure the Principal Investigator and other requested personnel, are available for any meeting or conference calls with the FDA concerning the approval of the Study Drug.

b. Institution will permit AIM or AIM's representatives to examine or audit the financial records related to such work, agreed upon times during regular business hours. , Institution shall provide AIM's representatives with reasonable access to such records. Information regarding Institution's systems, the information therein, and any incidental information that would be understood by a reasonable professional in the field to be confidential shall remain the property of Institution and will be treated as Institution's Confidential Information by AIM's representatives.

12. **Use of Names**

AIM and Institution shall not disclose publicly the terms of this Agreement, except to the extent required by academic policies or law. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Study, shall be made by a Party without the prior written approval of the other except as set forth in this section. Written approval shall not be required for the purposes of (i) announcing FDA authorization to initiate the Study following disclosure by Institution to AIM in a press release or (ii) when stating in part that the Study is supported by AIM in a press release.

13. **Independent Contractors**

Each party to this Agreement shall act as an independent contractor and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of the other party. Accordingly, the employee(s) of one party shall not be considered to be employee(s) of the other party, and neither party shall enter into any contract or Agreement with a third party which purports to obligate or bind the other party.

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14. **Complete Agreement. Amendment. Notice**

The Parties agree that this Agreement constitutes the sole, full, and complete Agreement by and between the Parties concerning the Protocol and supersedes all other written and oral agreements and representations between the Parties with respect to the items herein, except where in conflict with the Protocol, No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties. Any requests for changes or amendments or other notices or communications concerning this Agreement should be in writing or shall be deemed to have been given when mailed by personal delivery, nationally recognized courier, and shall be deemed effective only upon receipt, and forwarded to the following:

To AIM:	AIM ImmunoTech Inc, 2117 SW Highway 484 Ocala, Florida 34473 Attn: David Strayer, MD
To Institution:	Roswell Park Cancer Institute Corporation d/b/a Roswell Park Comprehensive Cancer Center Elm and Carlton Streets Buffalo NY 14263 Attn: VP, Clinical Research Services
With a copy to:	Attn: General Counsel (same address)
To Investigator:	Brahm Segal, MD Pawel Kalinski, MD, PhD (same address)

15. Compliance with Governing Law

The validity, interpretation, enforceability, and performance of this Agreement will be governed by and construed in accordance with the laws of the state of New York without regard to the application of conflict laws.

16. Reporting

Institution will provide AIM with the final study report (including all adverse events with severity and relationship to Study Drug) and any interim reports, such interim reports are prepared by Institution in its sole discretion ("Reports"). In order to maintain the integrity of the Study as required by the Protocol. Reports shall be considered Confidential Information and shall not be disclosed for any public dissemination without Institution's prior written consent.

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Such interim data reports may include, interim efficacy data necessary to maintain the integrity of the study as dictated by the protocol and interim analysis conducted by a statistician to inform on futility. Such interim and final reports are not intended for disclosure other than to AIM employees who require the information in order to complete their duties. For the avoidance of doubt, such interim and final data reports shall not be disclosed publicly and shall not be disclosed to non-AIM employees or consultants or for broad public dissemination without Institution's prior written consent; in addition all such reports may be submitted without Institution's consent by AIM to the FDA (or other regulatory agency or governmental authority) for purposes of Emergency Approval, Orphan Drug Status, Fast Track Status and New Drug Approval consideration upon receipt due to the urgency of the current COVID-I9 pandemic.

In addition, upon completion of the Study once the results are finalized, the results will be published in accordance with Section 9 of this Agreement in a fashion that is publicly available. AIM will be entitled to use the published results as they deem necessary. Nothing in this provision shall be deemed to provide AIM with editorial rights on the nature of the results that will be published.

Additionally, Institution agrees that to the extent that there is positive data that would support FDA Fast Track status or an Emergency Approval, Institution will submit the interim data to AIM, in Institution's reasonable discretion and to allow AIM to submit and file for necessary approval with the appropriate agencies.

17. **Insurance**

The Parties shall maintain insurance or a program of self-insurance in commercially reasonable amounts for the nature of services being performed.

18. **Binding, Effect**

This Agreement shall be binding upon the Parties, their legal representatives, successors, and assigns. The obligations of the Parties contained in Sections 5 (Adverse Events and Study subject Injury), 8 (Confidential Information), 9 (Publication), 10 (Intellectual Property), shall survive the termination or expiration of this Agreement.

19. **Waiver**

Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect.

20. **Assignment**

Neither Party shall assign or transfer any rights, obligations or duties under this Agreement.

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21. **Force Majeure**

21.1 Non-fulfillment, delay or omission by any of the Parties as regards of any and all of the obligations imposed by this Agreement will not be considered a breach of the Agreement, nor will it entail any liability when it is the result of Force Majeure. Force Majeure will be understood to comprise any extraordinary event, unforeseeable, or if foreseeable, an inevitable event, such as labor disputes, fire, mobilization, public health emergencies, insurrection, war, natural disasters, the prohibition of a government to not supply to a national company or organization, damages caused by the application of extraterritorial laws, embargoes and blockades imposed by third countries to any of the Parties, among others, that may occur or remain in force after the signing of this Agreement which may impede the partial or total fulfillment by the Parties of the obligations pursuant to this Agreement. The Party that invokes Force Majeure must notify the other Party in writing, within a period of thirty (30) days following the date of occurrence of the event or events constituting Force Majeure. This notification must be supported by a document issued for a competent authority and shall be duly certified. The document containing the above-mentioned information will be sent by courier delivery service within a period of thirty (30) days following the date of the initial notification.

21.2 If the event or events defined as causes determining an exemption from responsibility or Force Majeure persist for more than ninety (90) consecutive days, the Parties will, within the following sixty (60) days, meet in the most convenient place to examine all issues in the spirit of finding the best solution, and agree on all the steps, terms and conditions required to normalize the situation, without prejudice to the contracted obligations thus affected.

21.3 In the event that no such Agreement is reached on the steps, terms or conditions within the aforementioned period of sixty (60) days or in the event that such an Agreement is reached but not fulfilled under the terms and conditions agreed upon, the Party affected by the non-fulfillment may request the termination of the Agreement, and must be accepted by the other Party and will be in force the fulfillment of the pending payments.

22. **Severability**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by a party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

23. **Miscellaneous**

No delay by a Party to exercise any right or a non-exercise of it by the Party under this Agreement or the applicable law shall operate as a waiver of such right. The exercise in part of a right shall not preclude any other exercise or future exercise of such right or remedy deriving from it.

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24. **Authority**

Each of the Parties hereto certifies that the person signing below on such party's behalf has the authority to enter into this Agreement, and that this Agreement does not violate any existing agreement or obligation of such party.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the last date and year below written.

AIM ImmunoTech, Inc.

Name: s/Thomas K. Equels

Title: CEO, President

Date: 7/6/2020

Roswell Park Cancer Institute Corporation d/b/a Roswell Park Comprehensive Cancer Center

Name: s/Michael B. Sexton, Esq.

Title: Chief Administration Officer and General Counsel

Date: June 24, 2020

Read and Acknowledged as Payee:
Health Research Inc., Roswell Park Division

Name: s/John Blandino

Title: Director of Health Research, Inc.
Roswell Park Division
Date: 7/3/2020