CONFIDENTIAL DISCLOSURE AGREEMENT (TWO WAY)

THIS CONFIDENTIAL DISCLOSURE AGREEMENT (this "**Agreement**") is made and entered into as of the *11. January 2021* (the "**Effective Date**"), by and between:

Trials@Home Consortium Members, as defined below and listed in Exhibit 1;

and

("**Contract Partner**")

WHEREAS,

(A) The parties intend to disclose/receive confidential information for the purpose of facilitating discussions between the *Trials@Home* Consortium Members and the Contract Partner;

(B) The *Trials@Home* Consortium Members have formed a consortium under the Innovative Medicines Initiative 2 ("**IMI**") for the purpose of establishing the project called "Trials@Home: Center of Excellence – Remote Decentralised Clinical Trials " (IMI Grant Agreement No. *831458*) (the "*Trials@Home* **Action**") and are parties to the *Trials@Home* Consortium Agreement, as defined below, supported by the IMI2 Joint Undertaking;

(C) The *Trials@Home* Consortium Members have authorized *SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT - SARD* (the *"Trials@Home* **Mandate Holder**"), to execute this Agreement on behalf of the *Trials@Home* Consortium Members.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties hereto agree as follows:

1. DEFINITIONS

a) "**Affiliate**" shall mean any legal entity that is under the direct or indirect control of a party, under the same direct or indirect control as a party, or is directly or indirectly controlling a party, control taking any of the following forms: (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity; (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

b) "**Confidential Information**" shall mean any and all information that is disclosed on or after the Effective Date whether orally or in written, electronic or other tangible form by any of the *Trials@Home* Consortium Members, on the one hand, or by the Contract Partner, on the other hand (each referred to as a "**Disclosing Party**" and collectively as the "**Disclosing Parties**") under this Agreement Confidential Information shall only be disclosed to the individual *Trials@Home* Consortium Members upon their prior written approval (e-mail suffice) given to the *Trials@Home* Coordination Team. In case of the *Trials@Home* Consortium Members, Confidential Information shall be limited to comprise any of their information that relates to the *Trials@Home* Action. In case of Contract Partner, Confidential Information shall be limited to comprise to any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed *[]*. In any event, if personal data may be processed by the Parties hereunder, they shall be deemed Confidential Information.

c) "*Trials@Home* **Consortium Members**" shall mean the parties to the Innovative Medicines Initiative Consortium Agreement for Trials@Home: Center of Excellence – Remote Decentralised Clinical Trials effective as of 26 August 2019 ("*Trials@Home* **Consortium Agreement**") as listed at Exhibit 1.

2. PURPOSE OF DISCLOSURE

The Confidential Information is being disclosed for the purpose of facilitating discussions between

- *Trials@Home* Consortium Members and Contract Partner in order to engage in discussions regarding a collaboration between the *Trials@Home* Action consortium and the Contract Partner;

(the "**Purpose**").

3. MAINTENANCE OF CONFIDENTIALITY; NON-USE OBLIGATIONS

a) Each Disclosing Party's Confidential Information shall be kept confidential by each Recipient and, except as otherwise permitted herein, shall not be disclosed by the Recipient to any third party without first obtaining the Disclosing Party's prior written consent to such disclosure. Each Recipient shall protect the Confidential Information in the same manner it protects its own confidential information of a similar nature, which shall be at least a reasonable standard of care. Each Recipient may disclose the Confidential Information only to its officers, employees, consultants and/or Affiliates on a need-to-know basis, provided that it imposes on them restrictions on disclosure and use equivalent to those set forth herein. Each Recipient shall be liable for any damage caused by or resulting from any unauthorized disclosure of the Confidential Information by the Recipient's employees, consultants or Affiliates.

b) The Confidential Information shall not be utilized by the Recipient, except for the Purpose permitted herein, without first obtaining the Disclosing Party's prior written consent to such use.

4. EXCLUDED INFORMATION

Confidential Information which does not consist of personal data shall not include any information which:

a) at the time of disclosure is in the public domain;

b) after disclosure becomes part of the public domain, except through breach of this Agreement by Recipient;

c) Recipient can demonstrate by reasonable proof was in Recipient's or any of its Affiliates' possession prior to the time of disclosure by a Disclosing Party hereunder, and was not acquired directly or indirectly from a Disclosing Party;

d) Recipient can demonstrate by reasonable proof was developed by or on behalf of Recipient or its Affiliates independent of and without reference to the Confidential Information; or

e) becomes available to Recipient or its Affiliates from a third party who did not acquire such information directly or indirectly from a Disclosing Party and who is not otherwise prohibited from disclosing such information.

Confidential Information shall not be deemed to be or have become public knowledge merely because any part of such Confidential Information is embodied in general disclosures or because individual features, components or combinations thereof are known or become known to the public.

5. NOTIFICATION OF MANDATORY DISCLOSURE

a) Each Recipient may disclose that portion of Confidential Information that is required by law to be disclosed, provided that, to the extent practicable, the Disclosing Party is first given advance notice of the required disclosure and an adequate opportunity to seek appropriate legal relief to prevent such disclosure or limit use and further disclosure of the Confidential Information. Each Recipient shall cooperate with the Disclosing Party in seeking an appropriate relief or

remedy and shall use reasonable efforts to secure confidential treatment of any Confidential Information disclosed.

b) If, in the absence of such legal relief or other remedy, a Recipient is nonetheless required to disclose any part of the Confidential Information, Recipient may disclose such Confidential Information without liability hereunder, provided that, Recipient shall furnish only such portion of the Confidential Information which Recipient is legally required to disclose. For the avoidance of any doubt, if a Recipient is required to disclose Confidential Information pursuant to Recipient's obligations under the provisions of the Freedom of Information Act 2000 or any equivalent law or regulation in any other applicable jurisdiction, Recipient shall in all instances seek to apply the exemptions under that Act. The disclosure of personal data shall be subject to the applicable data protection legislation.

6. TERM

This Agreement shall come into effect on the effective date. It may be terminated with respect to further disclosures upon thirty (30) days' prior written notice. This Agreement shall cover Confidential Information disclosed within a period of four (4) years from the effective date. After such period, the obligations accrued under this Agreement shall survive for a period of ten (10) years."

7. NO OTHER OBLIGATION; NO LICENSE

This Agreement shall not be construed, by implication or otherwise, as an obligation to enter into any further agreement relating to the Confidential Information or as the grant of a license or other ownership rights other than to use the Confidential Information for the Purpose. Confidential Information disclosed by a Disclosing Party to a Recipient, as well as any right which could result from such Confidential Information, remains the exclusive property of that Disclosing Party.

8. NO REPRESENTATION OR WARRANTY

A Disclosing Party makes no representations or warranties either express or implied with respect to the Confidential Information and specifically disclaims any implied warranty of non-infringement or merchantability, satisfactory quality or fitness for purpose.

9. RETURN OF CONFIDENTIAL INFORMATION

At the request of the Disclosing Party or, at the latest, on completion of the Purpose, and in the absence of any further written agreement between the parties, each Recipient shall cease all use of the Confidential Information and shall promptly return to each Disclosing Party all of its Confidential Information which is in tangible form, except that each Recipient shall be permitted to retain one (1) copy of the Confidential Information so that any continuing obligations may be determined. The return of the Confidential Information will not affect Recipient's obligation to observe the confidentiality and non-use obligations set out in this Agreement. The provisions of this clause 9 shall not apply to copies of electronically exchanged Confidential Information or copies thereof which must be stored by Recipient according to the provisions of mandatory applicable law. The provisions of this clause shall not apply to copies of electronically exchanged Confidential

Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the Receiving Beneficiary according to provisions of mandatory law.

10. NO PUBLICITY

Subject to clause 5, the parties shall not directly or indirectly cause or permit (a) the oral or written release of any public statement referring to the existence or terms of this Agreement, or (b) any use of the other parties' name, logo or trademarks, without the other parties' prior written consent.

11. RIGHTS OF THIRD PARTIES

Each *Trials@Home* Consortium Member shall have a right to enforce the terms of this Agreement.

12. ASSIGNMENT

This Agreement shall not be assigned by Contract Partner without the prior written consent of the *Trials@Home* Consortium Members, whose consent may be withheld at the *Trials@Home* Consortium Members' sole discretion, and any purported assignment without such consent shall be void; provided, however, that Contract Partner may without such consent assign this Agreement in connection with the sale or transfer of all or substantially all of its business or in connection with a merger or other consolidation with another entity.

13. SEVERABILITY

If any provision of this Agreement is found to be invalid, illegal or unenforceable by a court of competent jurisdiction, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby. The parties shall in this case replace the invalid, illegal or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid, illegal or unenforceable provision.

14. ENTIRE AGREEMENT; AMENDMENTS; WAIVER

This Agreement contains the entire understanding between the parties hereto with respect to the subject matter contained herein and supersedes all prior written or oral communications, negotiations, understandings or agreements of any kind with respect to such subject matter. No amendment or modification of this Agreement shall be effective except by a written instrument referring to this Agreement and signed by authorized representatives of both parties. Failure by a party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor operate as a waiver in other instances.

15. GOVERNING LAW; HEADINGS

This Agreement shall be governed by and construed in accordance with the laws of Belgium, without giving effect to any of its conflict of laws principles. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in *[insert number of necessary duplicates]* in their own name and in case of Mandate Holder in addition in the name and on behalf of their respective Consortium Members as their duly authorized representative.

Trials@Home Mandate Holder

SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT - SARD (*[*]

Name: Catherine Baillis

Function: Head of Sanofi Partnering Operations

Place: Issy-les-Moulineaux

Date: 15 Jan 2021

Contract Partner (add name)

Name:

Function:

Place:_____

Date:_

EXHIBIT 1

(1) UNIVERSITAIR MEDISCH CENTRUM UTRECHT, whose administrative offices are at HEIDELBERGLAAN 100, po box: 85500, 3584 CX, UTRECHT, Netherlands;

(2) JULIUS CLINICAL RESEARCH BV, whose administrative offices are at Broederplein 41-43, 3703 CD, Zeist, Netherlands, Netherlands;

(3) STICHTING LYGATURE, whose administrative offices are at Jaarbeursplein 6, 3521 AL Utrecht, Netherlands;

(4) THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD, whose administrative offices are at University offices, Wellington Square, Oxford, OX1 2JD, United Kingdom;

(5) FH JOANNEUM GESELLSCHAFT MBH, whose administrative offices are at Alte Poststrasse 149 A-8020 Graz, Austria;

(6) MEDICAL RESEARCH NETWORK LIMITED, whose administrative offices are at Talon House, Presley Way, Crownhill, Milton Keynes, Buckinghamshire, MK8 0ES, United Kingdom;

(7) ECLINICALHEALTH LTD., whose administrative offices are at Logie Court, Stirling University Innovation Park, Stirling, FK9 4NF, Scotland, United Kingdom;

(8) UNIVERSITY OF DUNDEE, established by Royal Charter dated 20 July 1967 and a registered Scottish charity (charity number SC015096) and having its principal office at 149 Nethergate, Dundee, DD1 4HN, United Kingdom;

(9) SYDDANSK UNIVERSITET, whose administrative offices are at Campusvej 55, 5230 Odense M. ,Denmark;

(10) FUNDACION PARA EL FOMENTO DE LA INVESTIGACION SANITARIA Y BIOMEDICA DE LA COMUNITAT VALENCIANA, whose administrative offices are at Avd. De Cataluña, 21. 46022 Valencia, Spain;

(11) ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS (CERTH), whose administrative offices are at 6th km Charilaou-Thermi Road, Thessaloniki, 57001, Greece;
(12) VITAL TRANSFORMATION, whose administrative offices are at 107 Leopold III Laan, Wezembeek-Oppem, Belgium 1970, Belgium;

(13) STICHTING MLC FOUNDATION, whose administrative offices are at Amalia van Solmsstraat 46,2595 TB, Den Haag, Netherlands;

(14) FEDERATION INTERNATIONALE DU DIABETE REGION EUROPE AISBL, whose administrative offices are at chaussée de La Hulpe 166-C3, 1170 Brussels, Belgium;

(15) STICHTING UNITED PARENT PROJECTS MUSCULAR DYSTROPHY, whose administrative offices are at Koninginnelaan 69, 3905 GG Veenendaal, Netherlands;

(16) DREEM, whose administrative offices are at 7-11 boulevard Haussmann 75009 PARIS, France;

(17) UNIVERSITEIT UTRECHT, whose administrative offices are at Heidelberglaan 8, 3584 CS Utrecht, Netherlands;

(18) SANOFI-AVENTIS RECHERCHE & DÉVELOPPEMENT, whose administrative offices are at 54

rue La Boétie - 75008 Paris, France;
(19) ALLERGAN SALES LLC, whose administrative offices are at The Corporation Trust Center, 1209, Orange Street, Wilmington, DE 19801, United States;

(20) ASTRAZENECA AB, whose administrative offices are at SE-151 85 Södertälje, Sweden;

(21) BAYER AKTIENGESELLSCHAFT, whose administrative offices are at Müllerstraße 178, 13353 Berlin, Germany;

(22) BOEHRINGER INGELHEIM INTERNATIONAL GMBH, whose administrative offices are at Binger Straße 173 , 55216 Ingelheim am Rhein, Germany;

(23) COVANCE CLINICAL AND PERIAPPROVAL SERVICES SPRL, whose administrative offices are at Ave Marcel Thiry, 77 1200 Brussels, Belgium;

(24) IQVIA RDS FRANCE, whose administrative offices are at 151 – 161 Boulevard Victor Hugo, Saint-Ouen, 93400, France;

(25) JANSSEN PHARMACEUTICA NV (JANSSEN), a Belgian business corporation organized and existing under the laws of Belgium VAT No. BE-0403.834.160, RPR Antwerp, Division Turnhout, and with registered office at Turnhoutseweg 30, B-2340 Beerse, Belgium;

(26) MEDTRONIC INTERNATIONAL TRADING SARL, whose administrative offices are at Route du Molliau 31, 1131 Tolochenaz, Switzerland;

(27) NOVARTIS PHARMA AG, whose administrative offices are at Lichstrasse Basel, Switzerland;
(28) PFIZER LIMITED, whose administrative offices are at Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom;

(29) TAKEDA PHARMACEUTICALS INTERNATIONAL AG - TPIZ., whose administrative offices are at Thurgauerstrasse 130, 8152, Glattpark, Switzerland;

(30) TEVA PHARMACEUTICAL INDUSTRIES LIMITED, whose administrative offices are at 5 Basel St, Petah Tikvah, 49131, Israel;

(31) UCB BIOPHARMA SPRL, whose administrative offices are at Allée de la Recherche 60, 1070 Brussels, Belgium;

(32) MERCK KOMMANDITGESELLSCHAFT AUF AKTIEN, whose administrative offices are at 64293 Darmstadt Frankfurter strasse 250, Germany