

## Data Sharing Agreement

Between H. Lundbeck A/S  
Ottiliavej 9  
2500 Valby  
Denmark

And **[Recipient]**  
[Institution address]

This Clinical Data Sharing Agreement (the "Agreement") is entered into on [date] ("Effective Date").

Lundbeck and Recipient are hereinafter collectively referred to as the "Parties" and separately as a "Party".

### WHEREAS

- (A) Recipient has requested access to certain Clinical Data under Lundbeck's control with the purpose of conducting certain Research (as defined below).
- (B) Lundbeck intends to grant access to such Clinical Data (as defined in Exhibit A) to Recipient.
- (C) Recipient has appointed its employee [name/title] to conduct the Research on its behalf.

NOW IT IS HEREBY AGREED AS FOLLOWS:

### **1 Access to the Clinical Data**

- 1.1 Lundbeck shall grant access to the Clinical Data listed in Exhibit A to Recipient.
- 1.2 Lundbeck will provide Recipient with access to the Clinical Data via the Clinical Trial Data Transparency Software environment provided and hosted by SAS Institute A/S ("System").
- 1.3 Recipient shall not, and will ensure that its Researchers (as defined below) shall not:

- (a) download, save, edit, photograph, print, or transfer the whole or any portion of the Clinical Data from the System for either the approved use or for any other purpose;
- (b) remove, bypass, circumvent, neutralise or modify any technological protection measures of the System; or
- (c) share any username, password or other account details with a third party or otherwise provide a third party with access to the Recipient's account to the System.

## **2 Use of the Clinical Data**

2.1 Lundbeck hereby grants to Recipient a non-exclusive, royalty-free license to use the Clinical Data on the terms and conditions set out in this Agreement for the sole purpose of conducting the research specified in Exhibit B (the "Research"). As between Lundbeck and Recipient, any title or ownership of the Clinical Data, including any intellectual property embodied therein, shall remain with Lundbeck.

2.2 Recipient shall restrict access to and use of the Clinical Data to persons specified as engaged in conducting the Research (specified in Exhibit B) ("Researchers"). Recipient may not store, copy or use the Clinical Data at any facility outside the System. Recipient shall provide Lundbeck prior written notice of any replacement or additional Researcher and shall ensure that a replacement or additional Researcher acknowledges and agrees to the terms of this Agreement. A Researcher's access to and usage of the System will be subject to compliance by such Researcher with the terms of this Agreement and the access and usage conditions set forth on the System. Any Researcher may be denied access to the System, and Recipient shall be liable for any direct or indirect damages or liability arising from any non-compliance with the terms of this Agreement or the access and usage conditions. Lundbeck disclaims all liability to Recipient or to any Researcher in connection with access or use of the System.

2.3 Recipient may not use the Clinical Data for any purpose other than for conducting the Research, and may not expand or modify the scope of the Research as it relates to the Clinical Data without the prior written consent of Lundbeck.

2.4 Recipient shall comply with all applicable laws and regulations, and all written instructions from Lundbeck, in the handling, use and disposal of the Clinical Data.

- 2.5 Recipient shall not use the Clinical Data in any manner that confers on any third party any proprietary rights in or to the Clinical Data, or that creates obligations to disclose the results generated or derived by Recipient as the result of the Research under this Agreement to any third party (excluding disclosures pursuant to the publication provisions set forth in Clause 5).
- 2.6 Recipient acknowledges that the Clinical Data may contain sensitive personal information. Recipient shall maintain the Clinical Data in anonymized form and not attempt to re-identify any individual, including without limitation, clinical trial participants and trial staff. Recipient shall comply with all applicable laws and regulations relating to data protection and the privacy of subject health information.
- 2.7 Recipient agrees to provide Lundbeck with reasonable access to his/her files and to utilize and implement any methodology, statistical methods, formulae or other methods or tools used in conducting the Research for the purpose of reproducing the results of the Research.
- 2.8 Recipient agrees to immediately, no later than within twenty-four (24) hours, inform Lundbeck (and may also inform any regulatory authority) of any safety concerns identified while conducting the Research, and that Lundbeck may in its sole discretion take any action it deems relevant as a result of such information regarding safety, even in advance of publication of the results by Recipient. Lundbeck's pharmacovigilance contact details are provided in Exhibit C.
- 2.9 Recipient shall use the Clinical Data in compliance with Lundbeck's guidelines for Responsible Clinical Data Sharing as stated on the following website:  
[http://www.lundbeck.com/upload/global/files/pdf/corporate-responsibility/positions/Responsible\\_clinical\\_trial\\_data\\_sharing.pdf](http://www.lundbeck.com/upload/global/files/pdf/corporate-responsibility/positions/Responsible_clinical_trial_data_sharing.pdf)

### **3 Intellectual Property Rights and Clinical Data**

- 3.1 For the purpose of this Agreement, Intellectual Property Rights shall mean all intellectual property rights of any kind (whether or not they may be subject to registration and whether or not they are registered or are subject to an application for registration) generated or derived by Recipient as a result of the conduct of the Research or Recipient's use of the Clinical Data hereunder, including, but not limited to, rights to
- 3.2 inventions, discoveries, patents, utility models, supplementary protection certificates, copyrighted works, data and databases as well as rights in proprietary information, improvements, methods of use or delivery,

processes, trade secrets and know-how and all other rights or forms of protection of a similar nature.

3.3 Recipient shall promptly notify Lundbeck of any Intellectual Property Rights, and hereby grants to Lundbeck a non-exclusive, perpetual, fully paid-up, irrevocable, worldwide, royalty free license to any use of such Intellectual Property Rights, with the right to sublicense through multiple tiers.

3.4 Recipient hereby grants to Lundbeck an exclusive option to obtain, upon commercially reasonable terms, an exclusive license in all Intellectual Property Rights and data generated or derived by Recipient as the result of the Research and Recipient's access to the Clinical Data or eventually purchase Recipient's interest therein (the "Option"). The duration and other terms of the exclusive license or purchase shall be subject to good faith negotiation. This Option must be exercised within one hundred eighty (180) days after the date Lundbeck receives Recipient's notice with regard to the Intellectual Property Rights (the "Option Period"). Lundbeck may exercise the Option any time prior to the expiration of the Option Period. The period of negotiation of the exclusive license shall be for six (6) months beginning on the date of exercise of the Option by Lundbeck unless mutually extended by the parties. In the event that the Parties are unable to agree the terms of an exclusive license within the Option Period, or if Lundbeck does not exercise the Option, Recipient shall be entitled to negotiate license terms with third parties, provided, that such license terms take into account the non-exclusive license granted to Lundbeck subject to Clause 3.2 above.

3.5 Recipient agrees to obtain written agreements with all Researchers which assign, without additional consideration, all rights, title and interests in Intellectual Property Rights to Recipient for subsequent licensing to Lundbeck under this Agreement.

3.6 The obligations of this Clause 3 shall survive termination of this Agreement.

#### **4 Confidentiality**

4.1 Recipient shall hold in confidence any and all information and Clinical Data disclosed to Recipient by Lundbeck (the "Information"), except Information that Recipient can prove:

(a) was in the public domain at the time of disclosure;

- (b) has, after disclosure to Recipient, become part of the public domain through publication or otherwise, except by direct or indirect breach of this Agreement by Recipient;
- (c) was in Recipient's possession at the time of disclosure by Lundbeck, and was not acquired, directly or indirectly, from Lundbeck; or
- (d) was received by Recipient from a third party which is not legally prohibited from disclosing such information, provided, however, that such Information was not obtained by the said third party, directly or indirectly, from Lundbeck.

4.2 The obligations of this Clause 4 shall survive for a period of five (5) years after the termination of this Agreement.

## **5 Disclosure and Publication**

5.1 Notwithstanding Clause 4.1, and subject to this Clause 5, Recipient is obligated, consistent with the publication plans set forth in Exhibit B, to pursue publication or otherwise publicly disclose an article, manuscript, abstract, report, poster, presentation, or other material that includes the results of the use of the Clinical Data in the Research and identifying information regarding the Clinical Data, as would be reasonably required for purposes of publication in a peer-reviewed scientific journal. Such publication shall appropriately include citations or register identification numbers for the studies used in the analysis, note the source of the data as being attributed the data sharing of Lundbeck, and display the strengths and weaknesses of the Research methodology. Recipient shall provide Lundbeck with a reference citation upon publication or presentation, and may use Lundbeck's name solely for the purpose of the data and study attribution.

5.2 Recipient shall submit to Lundbeck a copy of the summary of results of the Research as well as a copy of any proposed publication no later than thirty (30) days prior to submission to a scientific congress or journal to give Lundbeck the opportunity for input regarding medical and scientific accuracy, supplementary scientific information, to object to any inclusion of the Information and to review for patentable subject matter.

5.3 The obligations of this Clause 5 shall survive for a period of five (5) years after the termination of this Agreement.

## **6 Term and termination**

- 6.1 This Agreement shall take effect on the Effective Date and shall expire on the completion of the Research, unless terminated earlier pursuant to Clause 6.2.
- 6.2 Either Party may terminate this Agreement in the event of any material breach on the part of the other Party upon fourteen (14) calendar days' written notice specifying the breach, unless such breach, if capable of cure, is cured within a period of seven (7) calendar days.
- 6.3 Any expiry or termination of this Agreement shall not affect any accrued rights or obligations of the Parties.
- 6.4 Upon termination or expiration of this Agreement, Lundbeck will terminate Recipient's access to the Clinical Data. Further, upon termination of this Agreement by Lundbeck pursuant to Clause 6.2 above, all tangible expressions, in any media, of the Information in Recipient's or a Researcher's possession shall be delivered to Lundbeck or, at Lundbeck's option, destroyed.

## **7 Assignment**

- 7.1 Without Lundbeck's prior written approval, Recipient shall not be entitled to assign or transfer any of Recipient's rights or obligations hereunder to any third party. Lundbeck may assign, transfer or subcontract its rights or obligations hereunder to any Lundbeck affiliate.

## **8 Miscellaneous**

- 8.1 Recipient acknowledges that the Clinical Data is provided 'as is' and without any representation or warranty, express or implied, as to the accuracy or completeness, including, without limitation, any implied warranty of merchantability or fitness for a particular purpose, or any warranty that the use of the Clinical Data will not infringe or violate any patent or other proprietary rights of any third party. Acceptance of Clinical Data will constitute acceptance by Recipient of liability for any damages and/or injuries related to Recipient's possession or use of the Clinical Data.
- 8.2 As the Clinical Data will be made available to Recipient by way of access to the System, Recipient acknowledges that SAS Institute A/S shall not be liable for any claims related to Recipient's access to or use of the System, and that Recipient may only access the System with the purpose of conducting the

Research. Specifically, Recipient may not access the System for internal business purposes or for production of clinical trial work.

**9 Governing Law and Dispute Resolution**

9.1 This Agreement and any dispute or claim arising out of or in connection herewith shall be governed by and construed in accordance with the laws of Denmark.

9.2 Any dispute or claim arising out of or in connection with this Agreement shall be finally settled by Danish arbitration in accordance with the "Rules of Procedure of the Danish Institute of Arbitration (Danish Arbitration)". The place of arbitration shall be Copenhagen, Denmark, and the arbitration proceedings shall be conducted in the English language.

**10 List of Exhibits:**

- Exhibit A: Description of the Clinical Data to be provided
- Exhibit B: Description of the Research
- Exhibit C: Lundbeck's pharmacovigilance contact information

Place: Place:  
Date: Date:

For and on behalf of: For and on behalf of  
H. Lundbeck A/S Recipient

By \_\_\_\_\_ By \_\_\_\_\_  
Name: Name:  
Title: Title: