

FOURTH AMENDMENT TO COMMERCIALIZATION AND SUPPLY AGREEMENT

This Fourth Amendment to Commercialization and Supply Agreement (the “**Amendment**”) is made as of November 28th, 2024, by and between medac GmbH, a *Gesellschaft mit beschränkter Haftung* organized and existing under the laws of Germany (“**medac**”), Medexus Pharma, Inc., a corporation existing under the laws of the state of Delaware (“**Medexus**”), and Medexus Pharmaceuticals Inc., a corporation existing under the federal laws of Canada (“**Parent**”). medac, Medexus, and Parent are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

WHEREAS, the Parties entered into that certain Commercialization and Supply Agreement as of February 2, 2021 (the “**Original Agreement**”) as amended by the First Amendment to Commercialization and Supply Agreement dated as of September 30, 2021 (the “**First Amendment**”), and as further amended by the Second Amendment to Commercialization and Supply Agreement dated as of August 1, 2022 (the “**Second Amendment**”) and the Third Amendment to Commercialization and Supply Agreement dated as of September 25, 2023 (the “**Third Amendment**”); the Original Agreement as amended by the First Amendment, the Second Amendment, and the Third Amendment is referred to herein as the “**Agreement**”);

WHEREAS, on June 5, 2024, the FDA issued the Acceptance Letter contemplated by the Third Amendment and, on June 6, 2024, medac delivered a copy of the Acceptance Letter to Medexus as contemplated by the Third Amendment; and

WHEREAS, the Parties desire to amend the Agreement as described in this Amendment.

NOW, THEREFORE, intending to be legally bound and in consideration of the mutual provisions set forth in this Amendment and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Defined Terms.** Capitalized terms used but not defined herein have the respective meanings assigned to them in the Agreement.
2. **Amendment to Article 1.** Article 1 of the Agreement is hereby amended as follows:
 - (a) By deleting the following Section 1.0.1:

“**Acceptance Letter**” shall have the meaning set forth in Section 3.1.3(iii)(a).”
 - (b) By adding the following Section 1.7.1:

“**Amendment Payment**” shall have the meaning given to such term in that certain First Amendment to Commercialization and Supply Agreement dated as of September 30, 2021, by and between the Parties (“**First Amendment**”).”
 - (c) By amending and restating Section 1.19 in its entirety as follows:

“**Clinical Superiority**” shall have the meaning set forth in Section 6.1.2(iii)(b).”
 - (d) By amending and restating Section 1.49 in its entirety as follows:

“**Extended FDA Approval Outside Date**” shall mean [redacted].”

(e) By adding the following Section 1.67.1:

“**Fourth Amendment Effective Date**” means November 28, 2024.”

3. **Amendment to Section 3.1.3.** Section 3.1.3 of the Agreement is hereby amended and restated in its entirety as follows:

3.1.3 Further Agreements. medac’s primary regulatory objective under this Agreement is to obtain the FDA Approval for the Product based on the submitted data set including written response to issues contained in the Initial NDA with a revised target PDUFA date to be determined by the FDA, and an Extended FDA Approval Outside Date of [redacted: date]. Since FDA Approval of the Initial NDA including [redacted: conditions] has not been received on or prior to the Fourth Amendment Effective Date and the FDA notified the Parties on or prior to the Fourth Amendment Effective Date that it will not grant Regulatory Approval of the Initial NDA that includes [redacted: conditions] without the receipt of additional Information that is (x) owned by medac, (y) planned to be generated by medac (“**Planned Available Information**”) as described in the development plan set forth in Schedule 3.1.3 (the “**Development Plan**”), or (z) additional Information that is not Planned Available Information (“**Additional Information**”), then this Section 3.1.3 is applicable and the Initial NDA will not be withdrawn and, instead, will be promptly pursued in accordance with Section 3.1.1 and this Section 3.1.3 to seek [redacted: commercially sensitive information]. The Parties agree that [redacted: commercially sensitive information] constitutes [redacted: commercially sensitive information] for purposes of this Agreement.

(i) medac shall use Commercially Reasonable Efforts to promptly (x) obtain such additional Planned Available Information based on the Development Plan-derived data and Additional Information including that specified in Schedule 3.1.3(i) (the “**FDA-Specified Information**”) as is necessary to support FDA Approval and/or Clinical Superiority [redacted: conditions], and (y) prepare and submit as an amendment or supplement as is appropriate for submission of such Information to the FDA by medac (or Medexus if the Initial NDA has transferred to Medexus). medac shall pay all costs associated with such amendment or supplement and/or sNDA and obtaining the Planned Available Information for activities included in the Development Plan together with any filing fees for such supplement or amendment, plus (subject to the next sentence) all costs associated with obtaining any other Additional Information or other activity that may be necessary to obtain FDA Approval and Clinical Superiority for the Product. Notwithstanding the foregoing, if the cost to obtain Additional Information or associated with any other activity that may be necessary to obtain FDA Approval and Clinical Superiority for the Product exceeds [redacted: dollar amount] (the “**FDA Additional Cost Amount**”), then, subject to the limitations set forth below, medac and Medexus shall each bear Fifty Percent (50%) of the amount in excess of the FDA Additional Cost Amount. In furtherance of the foregoing, medac shall provide to Medexus an invoice setting forth the cost of each PMR and PMC study included in the FDA-Specified Information promptly after the corresponding report of the contract research organization (the “**CRO**”) engaged by medac to conduct such PMR or PMC study is finalized by medac and such CRO, and Medexus shall pay its share of any amount in excess of the FDA Additional Cost Amount once the aggregate amount of all such invoices and any other invoices delivered by medac with respect to the cost to

obtain any other Additional Information or associated with any other activity that may be necessary to obtain FDA Approval and Clinical Superiority for the Product (each, an “**Additional Information Invoice**”) exceeds the FDA Additional Cost Amount no later than thirty (30) days after medac provides such Additional Information Invoices; *provided, however*, that Medexus shall not be required to pay more than [redacted: dollar amount] towards the FDA Additional Cost Amount. By way of example, [redacted].

(ii) If such supplement or amendment or sNDA submitted pursuant to Section 3.1.3(i) results in the FDA Approval of Clinical Superiority or non-inferiority on or before the Extended FDA Approval Outside Date, then a payment equal to such amounts that are due upon FDA Approval of Clinical Superiority or non-inferiority, less all Regulatory Milestone Payments already paid to medac under Section 6.1.2(iii), shall be paid by Medexus to medac as provided in Section 6.1.2(iii).

(iii) If, after the Fourth Amendment Effective Date, Medexus or medac receives a complete response letter or other indication that the Initial NDA is non-approvable (as agreed by the Parties) with an approval satisfying the requirement for a Regulatory Milestone Payment under Section 6.1.2(iii)(a) or Section 6.1.2(iii)(b), or the Initial NDA is not otherwise approved by the Extended FDA Approval Outside Date, the Parties will meet to discuss the best way to proceed and amend this Agreement with respect to one of the following courses of action: (a) the Parties will continue the current commercialization structure (i.e., medac is generally responsible for Manufacturing the Product, Medexus is generally responsible for Exploitation of the Product in the Medexus Territory and regulatory responsibilities are generally as set forth in Section 3.1.1), and medac shall continue paying for those costs set forth in the Development Plan, and Medexus shall continue making Regulatory Milestone Payments, as applicable, *provided* that the Parties shall adjust the value of Regulatory Milestone Payments and Sales Milestone Payments to reflect changes in the perceived value of the Product including as a result of increases or decreases in patient population, changes in treatment landscape, changes in competition and changes in market access, as a result of the delay of FDA Approval; or (b) the Parties will negotiate a co-development agreement, which shall contemplate that both costs and risk associated with pursuit of FDA Approval will be shared by the Parties, and Medexus shall continue making Regulatory Milestone Payments, as applicable, *provided* that the Parties shall adjust the value of Regulatory Milestone Payments and Sales Milestone Payments to reflect changes in the perceived value of the Product including as a result of increases or decreases in patient population, changes in treatment landscape, changes in competition and changes in market access, as a result of the delay of FDA Approval and the additional burden on Medexus with respect to allocation of the risk of the payment of a portion of the development costs. If the Parties cannot, after attempting in good faith, agree to one of the foregoing courses of action described in this Section 3.1.3(iii), and the resulting amendment to this Agreement, within one hundred and fifty (150) days after the earlier of: (x) the receipt after the Fourth Amendment Effective Date of a complete response letter, (y) the agreement of the Parties after the Fourth Amendment Effective Date that the Initial NDA is non-approvable, or (z) the Extended FDA Approval Outside Date, either Party may terminate this Agreement by delivering notice to the other Parties; *provided, however*, that, (I) in the event Medexus terminates this Agreement pursuant to this Section 3.1.3(iii), Medexus shall retain the Amendment Payment, and (II) in the event medac terminates this Agreement, medac shall refund Medexus Five Hundred Thousand Dollars (\$500,000) and Medexus shall retain the Amendment Payment. In either case, following termination of this Agreement,

medac may pursue negotiations and enter into any agreement with a third party regarding the subject matter of this Agreement.

4. **Amendment to Section 6.1.2(iii).** Section 6.1.2(iii) of the Agreement is hereby amended and restated in its entirety as follows:

“(iii) **Orphan Drug Designation and Clinical Superiority**

Subject to the occurrence of FDA Approval of the Initial NDA that occurs on or before the Extended FDA Approval Outside Date, Medexus shall pay medac an amount equal to, and in satisfaction of Medexus’ obligation under section 2 of the First Amendment to repay, the Amendment Payment.

(a) **FDA Approval of the Initial NDA, which does not include Clinical Superiority or non-inferiority.** Subject to the occurrence of the FDA Approval of the Initial NDA that occurs on or before the Extended FDA Approval Outside Date and includes at least 7-year exclusivity based on its Orphan Drug Designation but does not include Clinical Superiority or non-inferiority, Medexus shall pay medac the following amounts, in each case on or before the dates set forth below and in accordance with Section 6.1.5:

- (1) \$2,500,000, on or before June 30, 2025;
- (2) \$5,000,000, on or before October 1, 2025; and
- (3) \$7,500,000, on or before January 1, 2026.

(b) **FDA Approval of the Initial NDA, which includes Clinical Superiority** Subject to the occurrence of the FDA Approval of the Initial NDA that occurs on or before the Extended FDA Approval Outside Date and includes at least 7-year exclusivity based on its Orphan Drug Designation, and additionally includes data in Section 14 of the prescribing information using terminology stating clinical superiority pursuant to 21 C.F.R. Part 316 (“**Clinical Superiority**”), Medexus shall pay medac the following amounts , in each case on or before the dates set forth below and in accordance with Section 6.1.5:

- (1) \$7,500,000, on or before June 30, 2025;
- (2) \$15,000,000, on or before October 1, 2025; and
- (3) \$22,500,000, on or before January 1, 2026.

(c) **FDA Approval of the Initial NDA, which includes Non-inferiority (but not Clinical Superiority).** Subject to the occurrence of the FDA Approval of the Initial NDA that occurs on or before the Extended FDA Approval Outside Date and includes at least 7-year exclusivity based on its Orphan Drug Designation, and additionally includes non-inferiority (but not Clinical Superiority), Medexus shall pay medac the following amounts, in each case on or before the dates set forth below and in accordance with Section 6.1.5:

- (1) \$3,250,000, on or before June 30, 2025;
- (2) \$6,750,000, or before October 1, 2025; and
- (3) \$10,000,000, on or before January 1, 2026.

5. **Amendment to Section 6.1.2(iv).** Section 6.1.2(iv) of the Agreement is hereby amended and restated in its entirety as follows:

“**Generally.** No Regulatory Milestone Payment will be made more than once. For the avoidance of doubt and unless the Parties shall agree otherwise pursuant to Section 3.1.3(iii), if the FDA Approval of the Initial NDA occurs on or before the Extended FDA Approval Outside Date, medac shall be entitled to aggregate Regulatory Milestone Payments as and to the extent described in Section 6.1.2 which in any event shall not exceed \$55,000,000 in the aggregate (inclusive of amounts previously paid).”

6. **Amendment to Section 6.1.5.** Section 6.1.5 of the Agreement is hereby amended and restated in its entirety as follows:

“**6.1.5 Milestone Notices.** All payments due to medac under Section 6.1.2(i) and Section 6.1.2(ii) have been paid. medac shall notify Medexus promptly of the occurrence of any event triggering a Regulatory Milestone Payment specified in Section 6.1.2(iii), and Medexus shall notify medac promptly of the occurrence of any event triggering a Sales Milestone Payment specified in Section 6.1.3, and in each case no later than forty-five (45) calendar days after the occurrence of each such event. Together with its notice with respect to any event triggering a Regulatory Milestone Payment specified in Section 6.1.2(iii), and following its receipt of notice from Medexus, or if medac otherwise becomes aware, of the occurrence of any event triggering a Sales Milestone Payment specified in Section 6.1.3, medac shall issue an invoice for the relevant Regulatory Milestone Payment or Sales Milestone Payment, as applicable, in Dollars, which amount shall be subject to adjustment in accordance with Section 6.3. Medexus shall pay the amount due pursuant to such invoices within five (5) calendar days of issuance; *provided* (A) that Medexus may elect to temporarily defer the payment of the amount in excess of \$3,250,000 of the amount contemplated by clause (b)(1) of Section 6.1.2(iii), in whole or in part, for up to ninety (90) calendar days from the date the amount contemplated by clause (b)(1) of Section 6.1.2(iii) would otherwise be payable, (B) that Medexus may elect to temporarily defer the payment of the amounts contemplated by clauses (a)(2), (b)(2), or (c)(2) of Section 6.1.2(iii), in whole or in part, for up to one hundred twenty (120) calendar days from the date the relevant amount would otherwise be payable, and (C) that Medexus may elect to temporarily defer the payment of the amounts contemplated by clauses (a)(3), (b)(3), or (c)(3) of Section 6.1.2(iii), in whole or in part, for up to thirty (30) calendar days from the date the relevant amount would otherwise be payable, in each of cases (A), (B) and (C), with any such deferred whole or partial amount accruing interest at an annual rate of nine percent (9.0%) per annum (but with interest accruing on a daily basis) until paid. The invoices of medac shall be sent via email addressed to Medexus at US.Notices@Medexus.com or such other email address as Medexus may provide to medac from time to time for purposes of the invoicing of Milestone Payments.”

7. **Additional Amendments to Agreement.** The Parties acknowledge and agree that FDA Approval of the Product has been delayed beyond the date hereof, and certain terms and provisions of the Agreement that provided for actions to be commenced, or Minimum Amounts of Product to be purchased or Manufactured, or reports to be sent based on anticipated marketing and sales of the Product with reference to the Effective Date may need to be postponed. The Parties shall discuss in good faith adjustments to the dates by which such certain activities are to commence that are determined in the Agreement with reference to the Effective Date in a manner that preserves the original intent of the Parties as much as possible regarding advance planning. The sections of the Agreement containing such terms and provisions include but are not limited to [redacted]. Further to and without limiting the generality of the foregoing, the Parties hereby confirm their agreement that [redacted: commercially sensitive information]. Payment by Medexus for all other Products shall be made in accordance with the terms of this Agreement.
8. **Representations and Warranties.** medac and Medexus each represents and warrants to the other as follows:
- (a) **Organization.** It is a company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Amendment.
 - (b) **Authorization.** The execution and delivery of this Amendment and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary company action, and do not violate (i) such Party's charter documents, bylaws, or other organizational documents, (ii) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (iii) any requirement of any Applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.
 - (c) **Binding Agreement.** This Amendment is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).
 - (d) **No Inconsistent Obligation.** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Amendment, or that would impede the material fulfillment of its obligations hereunder.
9. **Agreement in Full Force and Effect.** Except as and to the extent expressly modified by this Amendment and sections 2 and 6 of the First Amendment, the Agreement shall remain in full force and effect in all respects.
10. **Counterparts; Facsimile Execution.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.
11. **Governing Law.** This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might

otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

[Signature page follows.]

The parties have executed and delivered this Amendment as of the date indicated in the first sentence of this Amendment.

MEDAC GMBH

By: “[redacted]”
Name: [redacted]
Title: [redacted]
Date: November 28, 2024

By: “[redacted]”
Name: [redacted]
Title: [redacted]
Date: November 28, 2024

MEDEXUS PHARMA, INC.

By: “Ken d’Entremont”
Name: Ken d’Entremont
Title: Executive Chairman
Date: November 28, 2024

MEDEXUS PHARMACEUTICALS INC.,
as guarantor of the payment and performance of the obligations of Medexus

By: “Ken d’Entremont”
Name: Ken d’Entremont
Title: Chief Executive Officer
Date: November 28, 2024