SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") and Dompé U.S. Inc. (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Dompé U.S. Inc. ("Dompé U.S.") is headquartered in San Mateo, California and is the North American subsidiary of Dompé farmaceutici S.p.A., ("Dompé farmaceutici"), a global pharmaceutical company incorporated in Italy (together, "Dompé"). Dompé farmaceutici is engaged in the research and development of treatments for ophthalmology, neurology, and pain. Dompé U.S. distributes and markets products developed by Dompé farmaceutici, including Oxervate, which is the only drug approved by the U.S. Food and Drug Administration to treat neurotrophic keratitis ("NK"). NK is a rare degenerative eye disease involving damage to the corneal nerve, which may progress to cornea perforation and permanent vision loss. Oxervate is a topical biologic containing cenegermin-bkbj, a recombinant form of human nerve growth factor.

B. The United States contends that Dompé U.S. submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").

C. When a Medicare beneficiary obtains a prescription drug covered by Medicare Part D, the beneficiary may be required to make a payment, which can take the form of a co-payment, co-insurance, or deductible (collectively, "co-pays"). Congress included co-pay requirements in the Medicare program, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare.

D. Dompé farmaceutici approached the U.S. Attorney's Office for the District of Massachusetts to voluntarily disclose conduct concerning Dompé U.S.'s interactions with and contributions to patient assistance foundations that pay the co-pays of certain patients, including Medicare beneficiaries ("patient assistance foundations"), which Dompé U.S. discovered following an internal compliance review. The Chief Executive Officer of Dompé farmaceutici at the time personally contacted the U.S. Attorney's Office for the District of Massachusetts and, with the assistance of counsel, initiated the voluntary disclosure.

E. At that time, neither the U.S. Attorney's Office nor other components of the U.S. Department of Justice were investigating such conduct. This was among the first voluntary disclosures made by a pharmaceutical company to the U.S. Attorney's Office for the District of Massachusetts pursuant to Justice Manual § 4-4.112, Guidelines for Taking Disclosure, Cooperation, and Remediation into Account in False Claims Act Matters, which had become effective on May 6, 2019. Dompé's disclosure was proactive and timely and identified individuals substantially involved in the relevant activity in accordance with Justice Manual § 4-4.112.

F. Dompé U.S. admits, acknowledges, and accepts responsibility for the following facts:

1. Dompé U.S. launched Oxervate in the United States in December 2018.

2. Prior to launch, employees expressed reservations about launching Oxervate in the United States before making a payment to a patient assistance foundation. In October and November 2018, Dompé U.S. employees spoke with representatives of the National Organization for Rare Diseases ("NORD"), a patient assistance foundation that paid the co-pays of certain patients, including Medicare beneficiaries. In November 2018, Dompé US and NORD executed an agreement for Dompe to make a contribution to an NK fund at NORD, which was launched in December 2018.

3. In October 2019, following conversations with Dompé U.S. employees, the PAN Foundation ("PANF"), another patient assistance foundation, opened an NK fund with an initial contribution from Dompé U.S.

4. Between 2019 and 2021, despite having an annual budgeting process through which Dompé U.S. determined patient assistance foundation funding amounts for the following year, Dompé sometimes approved mid-year increases to the foundation budgets set for NORD and PANF. Moreover, Dompé U.S. allocated funds to those foundations in its annual budget but held certain amounts in "reserve" so that Dompé U.S. could determine mid-year which of the patient assistance foundations were running low on funding and allocate the "reserve" accordingly. In certain instances, Dompé U.S. increased the foundation budget mid-year to contribute more to NORD and PANF than the amount that had been held in "reserve." In one instance, an increased mid-year budget for NORD

followed discussions between NORD and Dompé. Dompé U.S.'s compliance consultant cautioned Dompé U.S. employees about these mid-year "look-ins" to the status of the NK funds after the first year that Oxervate was on the market, advising that Dompé U.S. should not reverse engineer data from or about patient assistance foundation activity to inform Dompé U.S.'s contribution decisions.

5. In 2019, Dompé U.S. also solicited patient assistance foundation data directly from the foundations and from the specialty pharmacy that provided hub services to Dompé U.S. patients. This data was provided, directly or indirectly, to members of the company's Market Access team, which sat within Dompé U.S commercial organization, and certain individuals involved in the patient assistance foundation budgeting process. For instance, in November 2019, a Market Access employee and a Dompé U.S. consultant responsible for managing the company's relationship with patient assistance foundations exchanged information that each had respectively received from the specialty pharmacy and NORD in an effort to determine the number of Oxervate patients pending at NORD. The consultant, who reported directly to the prior Dompé U.S. General Manager (GM) at the time, was responsible for making—and did make—recommendations for patient assistance foundation budgets, and the consultant analyzed the data received from the foundations and the specialty pharmacy in connection with these recommendations.

6. On multiple occasions between 2019 and 2021, in contravention of the company's compliance program guidance, Dompé U.S. key account managers, responsible for sales of Oxervate, solicited and received information about patient assistance foundation coverage of specific patients from Dompé U.S. patient access managers. These communications included, for instance, requests to find out the status of certain patients trying to receive co-pay assistance from foundations.

7. After learning of an internal investigation into Dompé U.S.'s interaction with patient assistance foundations, two senior employees involved in the company's contributions to NORD and PANF failed to preserve data on their devices.

8. By 2022, Dompé U.S. implemented changes to its patient assistance foundation contribution practices. For instance, Dompé U.S. modified its procedures concerning interactions with and contributions to patient assistance foundations, including that the Dompé U.S. GM, who has since left the Company, could not be involved in foundation decision making or have access to foundation data, and that budgeting for foundation contributions be based on objective, documented criteria. Dompé U.S. also implemented enhanced procedures concerning the interactions between key account managers and patient access managers, including that they could not discuss foundations or foundation approval status.

G. The United States contends that it has certain civil claims against Dompé U.S. from October 1, 2018 through December 31, 2021 (the "Covered Period") for knowingly causing false claims and causing false statements to the United States in connection with Medicare reimbursement for Oxervate. Specifically, the United States contends that it has certain civil claims arising from the conduct described in Recital F above during the Covered Period where Dompé U.S. improperly paid Medicare beneficiary co-pays through NORD and PANF to induce the purchase of Oxervate, which violated the AKS and caused false claims to be submitted to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729. The conduct and time period described in Recitals F and G is hereinafter referred to as the "Covered Conduct."

H. Dompé U.S. received credit under the Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual § 4-4.112. Among other actions, Dompé made a voluntary self-disclosure, performed and disclosed the results of a thorough internal investigation, voluntarily produced significant volumes of documents (including evidence outside the United States), made available witnesses for interview (including two outside the United States), identified documents, current and former employees, and third parties most relevant to the United States' investigation, implemented appropriate remedial measures, and admitted and acknowledged Dompé U.S.'s conduct. Further, the disclosure of information was not under threat of discovery or investigation.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Dompé U.S. shall pay to the United States thirty-two million dollars ($32,000,000) ("Settlement Amount"), plus interest on the Settlement Amount at a rate of 4.5% per annum from June 29, 2026. Dompé U.S. shall pay the Settlement Amount, plus interest due, no later than 30 days after the Effective Date of this Agreement by electronic funds transfer,

pursuant to written instructions to be provided by the U.S. Attorney's Office for the District of Massachusetts. Of the Settlement Amount, $29,090,909 is restitution.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases Dompé U.S., together with its predecessors, and its current and former divisions, parents, subsidiaries, successors, and assigns, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Dompé U.S. waives and shall not assert any defenses Dompé U.S. may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. Dompé U.S. fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dompé U.S. has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Dompé U.S. agrees not to resubmit to any Medicare contractor or any state payer

any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

7. Dompé U.S. agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dompé U.S., its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) Dompé U.S.'s investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement; and

(5) the payment Dompé U.S. makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Dompé U.S., and Dompé U.S. shall not charge such

Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Dompé U.S. or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Dompé U.S. further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dompé U.S. or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dompé U.S. agrees that the United States, at a minimum, shall be entitled to recoup from Dompé U.S. any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dompé U.S. or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Dompé U.S. or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dompé U.S.'s books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

8. Dompé U.S. agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Dompé U.S. shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Dompé U.S. further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf. For the avoidance of doubt, Dompé U.S. reserves the right to assert as applicable the attorney-client privilege and work product protections.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Dompé U.S. agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Dompé U.S.'s successors, transferees, heirs, and assigns.

18. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date" of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: __________ BY: LINDSEY ROSS Digitally signed by LINDSEY ROSS Date: 2026.09.09 14:05:20 -04'00'

LINDSEY ROSS
BRIAN M. LAMACCHIA
Assistant United States Attorneys
U.S. Attorney's Office for the District of Massachusetts

DATED: __________ BY: SARAH ARNI Digitally signed by SARAH ARNI Date: 2026.09.09 10:27:32 -04'00'

SARAH ARNI
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/3/3036 BY: ____________________

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DOMPÉ U.S. INC.

/9/2026

DATED: __________ BY: Signed by: Shannon Sullivan
F1D48B425C6B4C6...

Shannon Sullivan
Chief Operating Officer for Dompé U.S. Inc.

/8/2026

DATED: __________ BY: Signed by: Gary Giampetruzzi
74953FAE67C7430...

Gary Giampetruzzi
Counsel for Dompé U.S. Inc.