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") (collectively, the "United States"), Ultragenyx Pharmaceutical Inc. ("Ultragenyx"), and Lisa Ruggiero ("Relator") (hereafter all collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Ultragenyx is a publicly traded Delaware corporation with its principal place of business in California. Ultragenyx is a pharmaceutical manufacturer that develops new therapies for patients with rare and ultra-rare diseases, including the drug Crysvita (burosumab-twza) ("Crysvita"), a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia ("XLH") in adult and pediatric patients six months of age and older.

B. XLH is a rare, inherited disorder characterized by low levels of phosphate in the blood which can lead to soft, weak bones. Features include bowed or bent legs, short stature, bone pain, fractures and dental abscesses. XLH can be difficult to diagnose and can be confused with other disorders that present with similar symptoms. In many instances, a genetic test is necessary to definitively diagnose XLH.

C. On July 19, 2021, Relator filed an action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Ruggiero v. Ultragenyx Pharmaceutical Inc*., Civil Action No. 1:21-cv-11176-ADB, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and analogous state law provisions (the "Civil Action"). The Civil Action alleges, *inter alia*, that Ultragenyx paid illegal remuneration in

exchange for referrals and to induce prescriptions and the purchase of Crysvita, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), and the False Claims Act.

D. On April 6, 2022, HHS-OIG issued OIG Advisory Opinion No. 22-06, which addressed a request by another entity to provide free genetic testing and counseling services under certain circumstances (the "OIG Advisory Opinion").

E. The United States contends that Ultragenyx caused the submission of claims for payment for Crysvita to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"), and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid").

F. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), prohibits drug companies from knowingly and willfully paying remuneration to induce a person to: (1) refer an individual to a person for the furnishing, or arranging for the furnishing, of any Medicare or Medicaid-reimbursed drug; or (2) to purchase or order, or arrange for the purchasing or ordering, of any Medicare or Medicaid-reimbursed drug.

G. Ultragenyx admits, acknowledges, and accepts responsibility for the following facts:

Ultragenyx understood that, in some cases, a positive genetic test for a genetic mutation consistent with XLH would be required for an insurer (including Medicare or Medicaid) to reimburse Crysvita prescribed to a patient, or for a healthcare provider ("HCP") to make a definitive diagnosis of XLH and prescribe Crysvita.

Ultragenyx entered into an arrangement with a genetic testing laboratory ("Laboratory") whereby Ultragenyx paid the Laboratory to conduct these tests—at no cost to HCPs or patients—and provide the results to the HCP. Ultragenyx separately paid the Laboratory to provide test results back to Ultragenyx and its commercial team used the results, in part, to find potential

Crysvita patients and their HCPs for follow up Crysvita marketing efforts. Ultragenyx referred to this program as its "sponsored" XLH testing program.

Ultragenyx sales personnel discussed the XLH testing program with HCPs and delivered order forms for the tests to HCP offices. The test results Ultragenyx received did not contain patient names but did contain the name of the HCP who ordered the test, a de-identified patient ID number, the date the test was ordered, and—once ready—the test result itself (collectively, "Results Reports"). Until April 2022, Ultragenyx received Results Reports and disseminated this information to its sales force with instructions to make sales calls for Crysvita to HCPs who ordered a test or, in particular, who had a patient with a positive test result. Ultragenyx's sales force followed up with HCPs regarding test results.

H. The United States contends that it has certain civil claims against Ultragenyx for engaging in the conduct described in Recital G during the period of February 1, 2019 through May 30, 2022 (hereinafter referred to as the "Covered Conduct"). In particular, the United States contends that, as a result of the Covered Conduct, Ultragenyx caused the submission of false claims to Medicare and Medicaid by paying remuneration: (1) to the Laboratory to induce the Laboratory to provide the Results Reports which referred Ultragenyx employees to HCPs for the furnishing or arranging for the furnishing of Crysvita through a targeted effort that resulted in Crysvita prescriptions reimbursed by Medicare and Medicaid; and (2) to beneficiaries in the form of covering the cost of the genetic tests, to induce their purchase of Medicare or Medicaid-reimbursed Crysvita. In April 2022, after becoming aware of the OIG Advisory Opinion and without conceding that its original program violated the law, Ultragenyx ceased providing Results Reports to its sales force and ceased using Results Reports for marketing purposes.

I. Ultragenyx will enter into separate settlement agreements (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states in settlement of the conduct

released in those separate Medicaid State Settlement Agreements. States with which Ultragenyx executes a Medicaid State Settlement Agreement in the form to which Ultragenyx and the States have agreed through a State Negotiating Team, or in a form otherwise agreed to by Ultragenyx and an individual State, shall be defined as "Medicaid Participating States."

J. With the exception of the Covered Conduct, Ultragenyx expressly denies the allegations of the Relator as set forth in the Civil Action.

K. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

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

TERMS AND CONDITIONS

1. Ultragenyx shall pay to the United States and the Medicaid Participating States, collectively, six million dollars ($6,000,000) plus interest accruing at an annual rate of 3.625% from May 26, 2023, until the date of payment ("Settlement Amount"). Of the Settlement Amount, $2,895,923.10 shall constitute restitution to the United States and $104,076.90 shall constitute restitution to the Medicaid Participating States. Ultragenyx will pay the Settlement Amount as follows:

a. Ultragenyx shall pay the United States $5,791,846.21 plus interest as accrued above ("Federal Settlement Amount") to the United States by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts no later than thirty (30) days after the Effective Date of this Agreement.

b. Ultragenyx shall pay $208,153.79 plus interest as accrued above to the Medicaid Participating States ("State Settlement Amount") pursuant to the terms of the Medicaid State Settlement Agreements.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Ultragenyx and as soon as feasible after receipt, the United States shall pay 18.5 percent of the Federal Settlement Amount ("Relator Share") to Relator by electronic funds transfer.

3. Ultragenyx has agreed to pay Relator's attorneys' fees and costs related to the Civil Action, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms set forth in a separate agreement being entered into simultaneously with the execution of this Agreement.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and conditioned upon the United States' receipt of the Federal Settlement Amount, the United States releases Ultragenyx, together with its current and former parents, divisions, 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.

5. Subject to the exceptions in Paragraph 6 below, and upon the United States' receipt of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Ultragenyx, together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them, from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from all liability, claims, demands, actions, or

causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator, her heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action, including claims for reasonable attorneys' fees, expenses, and costs under 31 U.S.C. § 3730(d).

6. Notwithstanding the releases given in Paragraphs 4 and 5 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.

7. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. Ultragenyx waives and shall not assert any defenses it 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.

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

10. Ultragenyx releases Relator from all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Ultragenyx, its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, or the corporate successors, attorneys, agents, and assigns of any of them would have standing to bring as of the date of this

Agreement, including any liability to Ultragenyx arising from or relating to the Civil Action and Relator's investigation and prosecution thereof.

11. 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 or carrier), or any state payer related to the Covered Conduct; and Ultragenyx 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.

12. Ultragenyx 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 Ultragenyx, 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 and any criminal investigation(s) of the matters covered by this Agreement;

(3) Ultragenyx's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal 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 payments Ultragenyx 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 Ultragenyx and it 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 Ultragenyx or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Ultragenyx 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 Ultragenyx 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. Ultragenyx agrees that the United States, at a minimum, shall be entitled to recoup from Ultragenyx 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 Ultragenyx or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Ultragenyx 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 Ultragenyx's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. 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 14 (waiver for beneficiaries paragraph), below.

14. Ultragenyx 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.

15. Upon payment by Ultragenyx of the Settlement Amount, the Parties shall promptly sign and file a Joint Stipulation of Dismissal pursuant to Federal Rule of Civil Procedure 41(a)(1). The Joint Stipulation of Dismissal shall state that: (1) claims for the allegations described in the Covered Conduct are dismissed with prejudice as to the United States; (2) all other claims in the Civil Action against Ultragenyx shall be dismissed without prejudice as to the United States; and (3) all claims in the Civil Action against Ultragenyx, including any claims for attorneys' fees and expenses under 31 U.S.C. § 3730(d), shall be dismissed with prejudice as to the Relator.

16. Except as provided above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

18. 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.

19. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

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

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

22. This Agreement is binding on Ultragenyx's successors, transferees, heirs and assigns.

23. This Agreement is binding on Relator's successors, transferees, heirs and assigns.

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

25. 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: 12/19/2023 BY: _____

AUGUSTINE M. RIPA
Senior Counsel for Health Care Fraud
Commercial Litigation Branch
Civil Division

DATED: 12/19/2023 BY: _____

BRIAN LAMACCHIA
DIANE SEOL
Assistant United States Attorneys
District of Massachusetts

DATED: _____ BY: SUSAN GILLIN Digitally signed by SUSAN GILLIN Date: 2023.12.18 15:59:21 -05'00'

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

ULTRAGENYX PHARMACEUTICAL INC.

DATED: Dec 6, 2023 BY: _____

EMIL D. KAKKIS, M.D., Ph.D.
President and Chief Executive Officer
Ultragenyx Pharmaceutical Inc.

DATED: 12/12/23 BY: _____

PAULA RAMER
Arnold & Porter Kaye Scholer LLP
Counsel for Ultragenyx

RELATOR LISA RUGGIERO

DATED: 12/5/23 BY: Lisa Ruggiero
LISA RUGGIERO

DATED: 12/5/23 BY: Gregg Shapiro
GREGG SHAPIRO
Gregg Shapiro Law, LLC
Counsel for Relator