FDA U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA CERTIFIED MAIL AND E-MAIL

July 19, 2023

Light Sciences Oncology
Attention: Llew Keltner, M.D., Ph.D., Chief Executive Officer (CEO)
Lisa Koch-Hulle, RAC, Regulatory Affairs Consultant
P.O. Box 178
Friday Harbor, Washington 98006

Re: Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "A Phase 2 Randomized, Double-blind, Placebo Controlled, Study of MR901 in Patients with Moderate to Severe Lower Urinary Tract Symptoms (LUTS) Due to Benign Prostatic Hyperplasia (BPH)" (NCT02326454)
FDA Reference Number: CDER-2022-105

Dear Dr. Keltner and Ms. Koch-Hulle:

The U.S. Food and Drug Administration (FDA) sent your company a letter dated February 22, 2022, alerting Light Sciences Oncology and Ms. Koch-Hulle to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine (a part of the National Institutes of Health) for the above-referenced clinical trial. We e-mailed that letter to Dr. Keltner on April 22, 2022. Light Sciences Oncology is the "responsible party"[1] for the above-referenced clinical trial, which is an "applicable clinical trial"[2] subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary

[1] *See* sections 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of "responsible party."
[2] *See* sections 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of "applicable clinical trial."

completion date[3] of the applicable clinical trial, unless the responsible party has submitted a timely certification of delay, a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.[4]

Pursuant to 42 CFR 11.44(c), a responsible party may submit a certification for delayed submission of results information for an applicable clinical trial that studies an FDA-regulated drug product not approved by FDA for any use before the primary completion date and for which the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval of the drug product. However, to be timely, any such certification for delayed submission of results information must be submitted before the standard submission deadline. On April 19, 2018, your company requested a delay in posting the results for this study, but your request for delayed submission was untimely under 42 CFR 11.44(c) because it was not made before the submission deadline specified under 42 CFR 11.44(a).

If a timely certification for delayed submission of results information is submitted under 42 CFR 11.44(c)(1), the deadline for submitting results information is 30 calendar days after the earlier of (1) the date on which FDA approves the drug product for any use that is studied in the applicable clinical trial, or (2) the date on which the marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days. With such certification for delayed submission of results information, the responsible party must submit results information not later than two years after the date on which the certification was submitted, except to the extent that 42 CFR 11.44(d) applies.

In our February 22, 2022, letter, we requested that your company review its records for this clinical trial and submit all required results information promptly. We also stated that we intended to further review and assess this clinical trial beginning 30 calendar days after you received our February 22, 2022, letter, and that we might take regulatory action if we determined that your company was not in compliance at that time.

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[3] *See* 42 CFR 11.10 for the definition of "primary completion date." See also section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. 282(j)(1)(A)(v)), which defines "completion date." As reflected in 42 CFR 11.10, the terms "primary completion date" and "completion date" are synonymous for the purposes of 42 CFR part 11.

[4] *See* sections 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. 282(j)(3)(E) and (H)) and 42 CFR part 11, subpart C for results information submission requirements.

FDA has determined that your company failed to submit results information for the applicable clinical trial referenced above, as required under section 402(j) of the PHS Act (42 U.S.C. 282(j)) and 42 CFR 11.48.[5] Pursuant to section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)), FDA is notifying you that your company is not in compliance with FDAAA's results information submission requirements, which include the requirements in 42 CFR part 11, and FDA is providing your company with the opportunity to remedy its noncompliance by submitting the required clinical trial results information within 30 calendar days after you receive this Notice of Noncompliance (Notice).

Because failure to submit clinical trial results information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)), FDA may initiate an administrative action seeking a civil money penalty against your company. Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. 333(f)(3)(A)), "[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil money penalty of not more than $10,000 for all violations adjudicated in a single proceeding."[6]

If your company does not submit the required clinical trial results information in the manner and format specified at http://prsinfo.clinicaltrials.gov or at https://clinicaltrials.gov/ct2/manage-recs/how-report within 30 calendar days after receiving this Notice, FDA may also seek additional civil money penalties against your company. Specifically, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following receipt of a [notice issued] under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil money penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected."

In addition to civil money penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

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[5] We acknowledge that on February 13, 2023, your company initiated the submission of results information for NCT02326454 to the National Library of Medicine's Protocol Registration and Results System; however, your company did not enter complete results information or did not complete the process for submitting results information, and the preliminary steps taken by your company do not constitute submission of results information under 42 CFR 11.44(a).

[6] The civil money penalty amounts in this Notice reflect the amounts listed in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

If you have any questions about this Notice, you may call Laurie Muldowney, M.D., at (301) 796-1571. Please have the FDA reference number provided at the top of this Notice available when you call. Alternatively, you may e-mail Dr. Muldowney at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

We request that your company submit a written response to FDA within 30 calendar days after you receive this Notice, stating the actions your company has taken in response to this Notice.

Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5342
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

Carol Cave

Carol Cave, B.S.
Acting Associate Commissioner for Regulatory Affairs
Office of Regulatory Affairs
U.S. Food and Drug Administration

Cc: (b) (4)

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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