



VIA CERTIFIED MAIL AND E-MAIL

Light Sciences Oncology  
Attention: Llew Keltner, M.D., Ph.D., Chief Executive Officer  
Lisa Koch-Hulle, RAC, Regulatory Affairs Consultant  
P.O. Box 1688  
Portland, Oregon 97207

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. 282(j)  
**FDA Reference Number: CDER-2022-105**  
NCT02326454

Dear Dr. Keltner and Ms. Koch-Hulle:

On July 19, 2023, the Food and Drug Administration (FDA) sent your company a Notice of Noncompliance (Notice Letter) regarding its failure to submit clinical trial results information for the above-referenced clinical trial to the ClinicalTrials.gov data bank. We have reviewed your company's explanation set forth in your August 17, 2023, written response to the Notice Letter, and have now concluded that there was no legal requirement for your company to submit results information for this clinical trial. Accordingly, it appears that your company has addressed the issues raised in FDA's letter.

Sincerely,

*{See appended electronic signature page}*

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

cc: Llew Keltner, M.D., Ph.D., Chief Executive Officer  
Light Sciences Oncology  
P.O. Box 178  
Friday Harbor, Washington 98006

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**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.**  
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/s/  
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LAURIE B MULDOWNEY  
11/22/2023 10:02:10 AM