

VIA UNITED PARCEL SERVICE AND E-MAIL

Baylor Research Institute
Attention: Jaime Walkowiak, J.D., Chief Operating Officer
Baylor Scott & White Research Institute (BSWRI)
2001 Bryan Tower
Dallas, Texas 75201

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2022-121
NCT03193853 and NCT02251431

Dear Ms. Walkowiak:

Based on an initial review of Food and Drug Administration (FDA) records, information from the ClinicalTrials.gov data bank operated by the National Library of Medicine (a part of the National Institutes of Health), and any available public information, it appears that Baylor Scott & White Research Institute is the “responsible party”¹ for the above-identified clinical trials, which appear to be applicable clinical trials² subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007, 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 completion date³ 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

¹ See section 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 section 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.”

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 section 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 identified potential noncompliance related to each of the clinical trials identified below:

- “Phase II Clinical Trial of Treatment With TAK-228 and TAK-117 to Inhibit Homologous Recombination (HR) Followed by Cisplatin and Nab Paclitaxel in Patients With Chemotherapy-pretreated Metastatic Triple Negative Breast Cancer,” evaluating the efficacy of TAK-228 and TAK-117, followed by cisplatin and nab paclitaxel, in subjects with metastatic triple negative breast cancer
- “MB001-067 A Prospective, Double Blind, Placebo Controlled, Parallel Group, Randomized Trial of Extended Release Exenatide versus Placebo (Cohort A) and A Prospective, Single Group, Open-Label, Blinded Outcome Trial of Extended Release Exenatide (Cohort B) in Diabetic Patients with Type 4 Cardiorenal Syndrome (EXTEND-CRS Trial) Amendment 3,” evaluating quantitative impact of exenatide extended release on myocardial injury summary score (MISS), kidney injury summary score (KISS), cardiac fibrosis, and cardiac strain in subjects with type 2 diabetes mellitus (T2DM) and at risk for diastolic heart failure (DHF) (Type 4 cardiorenal syndrome)

It appears that results information for the referenced applicable clinical trials have not been submitted to the ClinicalTrials.gov data bank. Your institution should review its records of these clinical trials and determine whether your institution submitted all required results information. If your institution determines that results information is required and due for these clinical trials, please submit the results information promptly.

Failure to submit clinical trial information⁵ required under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including information required under the regulations found 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)). Beginning 30 calendar days after you receive this letter, FDA intends to further review and assess the above-identified clinical trial. If FDA determines that you failed to submit any clinical trial 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, you may receive from FDA a Notice of Noncompliance,⁶ and FDA may thereafter initiate an administrative action seeking a civil money penalty.⁷ In addition to civil money

⁵ See section 402(j)(1)(A)(iv) of the PHS Act (42 U.S.C. 282(j)(1)(A)(iv)) and 42 CFR 11.10 for the definition of “clinical trial information.”

⁶ See section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

⁷ Pursuant to section 303(f)(3)(A) of the Federal Food, Drug, and Cosmetic Act (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 monetary penalty of not more than \$10,000 for all violations adjudicated in a single proceeding.” Moreover, 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

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.

As requested, please review institution's clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. You can access the ClinicalTrials.gov website at <https://register.clinicaltrials.gov>. If you have any questions about this letter, you may call Miah Jung, Pharm.D., M.S., at (240) 402-3728. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may e-mail FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions you have taken in response to this letter. If you believe that your institution has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration.

within the 30-day period following notification 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 monetary penalty of not more than \$10,000 for each day of the violation after such period until the violation is corrected.” These civil money penalty amounts reflect the amounts found 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.

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

Miah Jung, Pharm.D., M.S.
Branch Chief
Compliance Enforcement Branch
Division of Enforcement and Postmarketing Safety
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5352
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

{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: Joyce A. O'Shaughnessy, M.D., Baylor Scott & White Research Institute

Peter A McCullough, M.D., MPH, Baylor Scott & White Research Institute

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/

LAURIE B MULDOWNY
10/18/2022 06:59:47 AM