



VIA UNITED PARCEL SERVICE AND E-MAIL

Immedica Pharma AB
Attention: Greg Dombal, Authorized Representative for Immedica Pharma AB
Solnavagen 3H
Stockholm, Sweden 113 63
SWEDEN

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2026-127
NCT02561234, NCT03371979, and NCT03378531

Dear Mr. Dombal:

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 Immedica Pharma AB is the “responsible party”¹ for the above-identified clinical trials, which appear to be “applicable clinical trials”² 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

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.” We recognize that Aeglea Biotherapeutics is listed as the responsible party for these clinical trials in the ClinicalTrials.gov data bank. However, public records show that Immedica Pharma AB acquired the global rights to pegzilarginase and related assets from Aeglea Biotherapeutics (<https://www.immedica.com/en/press/immedica-acquires-global-rights-pegzilarginase-aeglea-2146911>). FDA records dated August 9, 2023, show that Aeglea Biotherapeutics transferred ownership of IND 127774 to Immedica Pharma AB. Accordingly, Immedica Pharma AB appears to be the responsible party for these clinical trials.

Accordingly, Immedica Pharma AB appears to be the responsible party for these clinical trials.

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.”

date³ of the applicable clinical trial, unless the responsible party has submitted a timely certification of delay, request for an extension for good cause, or request for a waiver of the requirements for submission of results information.⁴

We note your company submitted a timely certification for delayed submission of results information under 42 CFR 11.44(c)(1) for NCT02561234. When a timely certification for delayed submission of results information is submitted under 42 CFR 11.44(c)(1), results information must be submitted no later than two years after the date on which the certification was submitted. See 42 CFR 11.44(c)(2).⁵ Notwithstanding that deadline, results information must be submitted sooner if 1) FDA approves the drug product for any use that is studied in the applicable clinical trial or 2) the marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days; if either of these two scenarios occurs, results information must be submitted within 30 calendar days of such event. See 42 CFR 11.44(c)(1).

FDA has identified potential noncompliance related to the above-identified clinical trials, titled as follows:

- “A Multiple Dose, Dose Escalation Trial of AEB1102 (Co-ArgI-PEG) in Patients with Advanced Solid Tumors”
- “A Phase 1/2 Study of Pegzilarginase (AEB1102, Co-ArgI-PEG) in Combination With Pembrolizumab in the Treatment of Patients with Extensive Disease (ED) Small Cell Lung Cancer (SCLC)”
- “An Open-label, Multicentre Extension Study to Evaluate the Long-Term Safety, Tolerability, and Effects of Intravenous AEB1102 in Patients with Arginase I Deficiency Who Previously Received Treatment in Study CAEB1102-101A”

It appears that results information for the referenced trials has not been submitted to the ClinicalTrials.gov data bank.⁶ Moreover, it appears that your company failed to update the

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.

⁵ The regulation contains an exception, not applicable here, regarding the submission of partial results information. 42 CFR 11.44(c)(2) and (d).

⁶ We acknowledge that, as recently as July 25, 2023, your company entered results information for NCT02561234 and NCT03371979, into the National Library of Medicine Protocol Registration and Results System (PRS); however, your company did not complete the process for submitting results information, and the

clinical trial registration information with any changes, including the responsible party contact information for NCT02561234 as required under 42 CFR 11.64(a)(1)(i)(A).⁷ Moreover, it appears that your company failed to update the responsible party contact information for these clinical trials, NCT03371979 and NCT03378531, as required under 42 CFR 11.64(a)(1)(ii)(L).⁸ Your company should review its records of these clinical trials and determine whether your company submitted all required information. If your company determines that information is required and due for these clinical trials, please submit the information promptly.

Failure to submit clinical trial information⁹ required under section 402(j) of the 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 trials. If FDA determines that your company has 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, your company may receive from FDA a Notice of Noncompliance,¹⁰ and FDA may thereafter initiate an administrative action seeking a civil money penalty.¹¹ In addition to civil money penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result

preliminary steps taken by your company do not constitute submission of results information under 42 CFR 11.44(a).

⁷ For applicable clinical trials initiated before January 18, 2017, such as the referenced clinical trial, NCT02561234, section 402(j)(4)(C)(i)(I) of the Public Health Service Act (42 U.S.C. 282(j)(4)(C)(i)(I)) generally requires the responsible party to submit updates not less than once every 12 months to reflect any changes. See also 42 CFR 11.64(a)(1)(i)(A). If your company is no longer the responsible party for this clinical trial, your company should notify FDA and must update this information in the ClinicalTrials.gov data bank.

⁸ For applicable clinical trials initiated on or after January 18, 2017, such as the referenced clinical trials, NCT03371979 and NCT03378531, 42 CFR 11.64(a)(1)(ii)(L) requires that responsible party contact information be “updated not later than 30 calendar days after a change in the responsible party or the contact information for the responsible party.” If your company is no longer the responsible party for this clinical trial, your company should notify FDA and must update this information in the ClinicalTrials.gov data bank.

⁹ 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.”

¹⁰ See section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

¹¹ 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 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 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.

in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

As requested, please review your company's clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. We also request that you review all applicable clinical trials for which your company is the responsible party to ensure compliance with all ClinicalTrials.gov registration and results information submission requirements. You can access the ClinicalTrials.gov website at <https://register.clinicaltrials.gov>.

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 company has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration.

Your written response, and any questions or concerns regarding this letter, should be sent via e-mail to the FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

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: Mattias Rudebeck, Vice President, Head of Global Integrated Evidence Generation
Immedica Pharma AB

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 MULDOWNNEY
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