



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

VIA UNITED PARCEL SERVICE

April 27, 2021

Acceleron Pharma, Inc.
Attention: James V. Desiderio, Ph.D.
128 Sidney Street
Cambridge, Massachusetts 02139

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for “A Phase 2 Randomized, Double-Blind Study of Dalantercept and Axitinib Compared to Placebo and Axitinib in Patients with Advanced Renal Cell Carcinoma” (NCT01727336)
FDA Reference Number: CDER-2020-110

Dear Dr. Desiderio:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 20, 2020, which you received on July 21, 2020, alerting you 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. Acceleron Pharma, Inc. is the “responsible party”¹ for the above-referenced clinical trial, which is an “applicable clinical trial”² that is 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 completion date of the applicable clinical trial, unless the responsible party has submitted a certification of delay, a request for an extension of good cause, or a request for a waiver of the requirements for submission of results information.³

In our July 20, 2020, 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

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 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 submission requirements.

received our July 20, 2020, letter, and that we might take regulatory action if we determined that your company was not in compliance at that time.

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 Public Health Service Act (PHS Act) (42 U.S.C. 282(j)) and 42 CFR 11.48. 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 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 information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)) 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 monetary 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 monetary penalty of not more than \$10,000 for all violations adjudicated in a single proceeding.”⁴

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 monetary 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 monetary 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 monetary 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.

If you have any questions about this Notice, you may call David C. Burrow, Pharm.D., J.D., at (301) 796-5632. Please have the FDA reference number provided at the top of this Notice available when you call. Alternatively, you may e-mail Dr. Burrow at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

⁴ The civil monetary 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.

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.

David C. Burrow, Pharm.D., J.D.
Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5348
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Judith McMeekin".

Judith McMeekin, Pharm.D.
Associate Commissioner for Regulatory Affairs
Office of Regulatory Affairs
U.S. Food and Drug Administration