Author’s response to reviews

**Title:** A Phase 1, Randomized, Open-Label, Single-Dose Study to Assess the Relative Bioavailability of a Subcutaneous Dose of FKB327 When Administered Using a Prefilled Syringe, a Prefilled Auto-Injector, or a Vial with Disposable Syringe in Healthy Subjects

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**Version:** 2  **Date:** 03 Dec 2019

**Author’s response to reviews:**

Re: Manuscript PHAT-D-19-00206R1

William Spenceley Jones
Assistant Editor
BMC Pharmacology and Toxicology

Dear Dr. Spenceley Jones,

Please find enclosed a revised copy of our manuscript, PHAT-D-19-00206R1, entitled “A Phase 1, Randomized, Open-Label, Single-Dose Study to Assess the Relative Bioavailability of a Subcutaneous Dose of FKB327 When Administered Using a Prefilled Syringe, a Prefilled Auto-Injector, or a Vial with Disposable Syringe in Healthy Subjects.” We would like to thank the editors for their insightful comments, and we hope the amendments satisfy their concerns. All changes have been made in the manuscript. A point-by-point response to the editors’ comments is attached. We appreciate the opportunity to publish in BMC Pharmacology and Toxicology. Please feel free to contact me with any questions or concerns.

Sincerely,

Jim Bush MBChB, PhD, MRCS, FFPM

Executive Medical Director
Global Head, Clinical Pharmacology Physicians
Covance Clinical Research Unit Limited
EDITOR:

1. The last section of the abstract should be Trial Registration: listing the trial registry and the unique identifying number, e.g. Trial registration: Current Controlled Trials ISRCTN73824458, as well as the date of registration. Please note that there should be no space between the letters and numbers of the trial registration number. If registration took place after the first participant was enrolled, please state also “Retrospectively registered” at the end of this section

   Trial Registration information has now been added to the end of the Abstract (line 47, page 3). Registration took place before the first participant was enrolled. Thank you.

2. Please rename your 'Introduction' section 'Background.'

   We have made this change (Background section, line 52, page 4). Thank you.

3. Please provide a complete Declarations section before the references, including an Availability of data and materials section (we appreciate that you may have supplied some of the information in the body of the manuscript). Please note that we require all of the sections to be present (unless stated optional), as well as a “Declarations” heading.

   We apologize for the omission of any required elements. We have added information to the Declarations section (line 346, pages 17-19) before the references, as requested. As for the Availability of Data section, we have left it as is (data available from corresponding author upon request), since this is a Phase 1 Study and therefore registration does not appear on the public website. We have provided the Trial Registration information, including registry name, unique identifying number and date of registration, as requested at the end of the abstract. Further information is below for your reference:

   EU Clinical Trials Registry EudraCTN2014-004469-26

   Study registered with EudraCT: 14 October 2014

   First patient in (1st ICF signed): 01 October 2015

   End of Trial: 07 May 2016

   Results submitted to EudraCT: 25 April 2017

   Results posted on EudraCT (not public view): 11 May 2017

4. Please represent authors' names using their full initials, not their full name, in the Authors’ Contributions section. If there are any duplicated initials, please differentiate them to make it clear that the initials refer to separate authors.
Authors' names are represented using their full initials the Authors’ Contributions section (line 404, page 19). Thank you.

5. Please include a statement in the Authors' contributions section to the effect that all authors have read and approved the manuscript and ensure that this is the case.

We apologize for this omission. We have added this statement to the Authors' contributions section (line 408, page 19).

6. Figure files should contain only the image/graphic, as well as any associated keys/annotations. If titles/legends are present within the figure files, please remove them and provide them in a separate section with the heading 'Figure Legends' after the references.

Thank you for pointing this out. We have added a section entitled ‘Figure Legend’ after the references (line 441, page 21) to reflect the title and legend of the one figure within the manuscript.

7. At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files. Please ensure that all figures, tables and additional/supplementary files are cited within the text.

Thank you for all of the suggestions. We have incorporated the necessary changes and will upload the final, clean manuscript without any tracked changes, comments, highlights, strikethroughs or text in different colours.