Author’s response to reviews

Title: Rational, Objectives and Design of PURE, a Prospective Registry of Patients with Moderate to Severe Chronic Plaque Psoriasis in Canada and Latin America

Authors:

Kim A Papp (submission@jssresearch.com; kapapp@probitymedical.com)
Melinda Gooderham (mjgooderham@gmail.com)
Jennifer Beecker (jbeecker@rogers.com)
Charles W Lynde (derma@lynderma.com)
Isabelle Delorme (docteure@dredelorme.com)
Ignacio Dei-Cas (ideicas@hotmail.com)
Lorne Albrecht (lalbrecht@primus.ca)
Emmanouil Rampakakis (erampakakis@jssresearch.com)
John S Sampalis (jsampilis@jssresearch.com)
Antonio Vieira (antonio.vieira@novartis.com)
Shamiza Hussein (shamiza.hussein@novartis.com)
Lenka Rihakova (lenka.rihakova@novartis.com)

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Referee comments: Rational, Objectives and Design of PURE, a Prospective Registry of Patients with Moderate to Severe Chronic Plaque Psoriasis in Canada and Latin America

Date sent: 2019-01-06

The authors thank the Editor and the Reviewer for their thoughtful comments. Our point-by-point response to their comments is given below.
1. We noticed that you did not include a response to the reviewer's report. We feel that the reviewer has addressed an important point regarding the description of the exclusion criteria that is currently included in your manuscript. Please find the reviewer's report below. In order to address the reviewer's report effectively, please can you please provide more details regarding the exclusion criteria for this study protocol? Please ensure any elaborations are included in the Methods section of your manuscript

Response: Thank you for your comment. We did not respond to Aldona Pietrzak’s note on the exclusion criteria as he included it only as a note and had already approved the manuscript. We apologize for the misunderstanding.

Kindly note that this was an observational registry and we collected data from real-world patients hence we did not have any stringent exclusion criteria other than the two that have been mentioned in the manuscript.

2. Please also describe the consent procedure that you will undertake in the Ethics approval and consent to participate section of your manuscript

The following text on the informed consent process has been added to the manuscript:

“Novartis will provide to treating physicians or other involved medical professionals in a separate document a proposed informed consent form that complies with the Declaration of Helsinki principle and regulatory requirements and is considered appropriate for this study. The physician are instructed to keep the original informed consent form signed by the patient and a signed copy is also given to the patient. Eligible patients may only be included in the study after providing written (witnessed, where required by law or regulation), IRB/EC-approved informed consent, or, if incapable of doing so, after such consent has been provided by a legally acceptable representative of the patient. In cases where the patient’s representative gives consent, the patient should be informed about the study to the extent possible given his/her understanding. If the patient is capable of doing so, he/she should assent by personally signing and dating the written informed consent document or a separate assent form. Informed consent must be obtained before any data are collected. The process of obtaining informed consent should be documented in the patient source documents.”

We have also provided all initial approvals of all participating sites. For every site participating in this study, an ICF has been review and approved by an EC so site can enroll patients.

3. We notice that you have presented your abstract at American Academy of Dermatology 74th Annual Meeting March 4-8, 2016 Washington, DC:
4. In the section 'Funding', please also describe the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Response: We have modified the ‘Funding’ section and added the role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

5. We note that authors Antonio Vieira, Shamiza Hussein and Olivier Chambenoit have not been included in the Authors’ Contributions section. The individual contributions of ALL authors to the manuscript should be specified in the Authors’ Contributions section.

Response: Thank you for the comment; we have now added the contributions of Antonio Vieira and Shamiza Hussein to the author contributor section. The contributions of Olivier Chambenoit were already included however there was a typing error (mentioned initials as OL instead of OC), we have corrected that now.

6. We note that you have included the initials "OL" in the Authors' Contributions section of your manuscript. We also note that these initials do not correlate with any of the authors listed. Please clarify whether this is a typing error or if this is an author that has not been listed in the author list. If you choose to change your author list you will need to fill out a change in authorship form and send it by email to the Editorial office to be approved by the Editor.

Response: Thank you for the comment; the OL initials were indeed a typing error. We have corrected that now and mentioned OC instead of OL.

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.

Response: We have uploaded the manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colors.