Response to Correspondence ALL-2023-01107 “Short-course subcutaneous treatment with PQ Grass strongly improves symptom and medication scores in grass allergy”

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Competing Interest Statement
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This randomized, double-blind, placebo-controlled study was designed to evaluate the short-term efficacy of pre-seasonal subcutaneous administration of PQ Grass compared to placebo during a single grass pollen season. Separate long-term Phase III studies are being planned to evaluate the long-term efficacy and safety of PQ Grass, as it is generally accepted that the evaluation of a sustained efficacy response requires three years of AIT treatment. During this study, the safety and tolerability of PQ Grass was defined as a secondary endpoint and was extensively evaluated during the study and included safety follow-up up to 6 months after the last dose for all study participants. This aligns with general regulatory requirements for the duration of safety follow-up in short-term AIT studies. This study also applied an intensive evaluation of solicited adverse events using a detailed questionnaire after administering each subcutaneous injection. In addition, subjects remained at the clinical sites for a minimum of 30 minutes after each dose to evaluate the occurrence of any local and systemic AEs.

Furthermore, a telephone safety call was performed approximately 24 hours, 4 and 7 days after each injection to inquire about any adverse events using a telephone script. Finally, safety was assessed three and six months following the last injection. These intensive safety monitoring procedures applied in the study have contributed to relative high reported incidences of adverse events for both the active and placebo treatment groups.

Furthermore, an extensive panel of molecular, cellular and humoral biomarkers was evaluated as a part of exploratory efficacy endpoints analysis in order to understand underlying immunological mechanisms and their relationship to the administered PQ grass allergen immunotherapy (AIT). A summary of the main findings related to the molecular mechanism induced by PQ Grass AIT are presented in the peer-reviewed manuscript “Peripheral blood mononuclear cell transcriptome profile in a clinical trial with subcutaneous, grass pollen allergoid immunotherapy” recently accepted for publication in Clinical and Experimental Allergy [1]. Furthermore, as part of this study, a comprehensive biomarker analyses was performed evaluating the cellular and humoral effects of PQ Grass conventional and extended regimens vs placebo. A manuscript summarizing these extensive biomarker findings is being finalized and will be published shortly in a peer-reviewed journal.

References