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**MJP2 Reporting Period Progress Report (4) – Q4 2022**

January 15, 2023

1. % of completion and work done during project period:

Given the unanticipated delays by the ongoing FDA clinical hold we have only performed approximately 5% of the work initially proposed in the statement of work (SOW).

During this reporting period the contracted CRO, Alira, met with the investigators at each clinical site that has completed Site Qualification Visits (Ann Arbor, MI; Tampa, FL; and Phoenix, AZ) to update them on the statuses of the clinical hold and protocol development, and communicated the plan to share the amendment as soon as available. Alira also communicated to investigators a provisional plan to resume contract negotiations by the second quarter of 2023 as long as the clinical hold is removed.

2. Description of Problems and Delays:

In September 2022, an FDA response was received which requested a full protocol amendment prior to reviewing a release on the clinical hold. A protocol amendment was developed and returned to the FDA in November. At the end of December, we received a response from the FDA indicating the continuation of the clinical hold, citing '21 CFR 312.42(b)(2)(i): Insufficient information to assess risks to human subjects' in our proposed protocol. One of the FDA's primary concerns is with the proposed self-titration in the protocol. The FDA response letter has been included along with this report. MAPS will be taking the FDA's suggestion and requesting a Type A meeting with the FDA to discuss the latest letter. Veteran advocate, Anton Harb, has agreed to join MAPS in this Type A meeting to express the view that veterans want self-titration rather than standardized dosing. MAPS is also exploring the option of filing a Formal Dispute Resolution Request. Until the clinical hold is removed, any non-clinical hold related activities will be tabled in our effort to remove the clinical hold as soon as possible.

3. Statement regarding any deviation from SOW:

At this reporting period, the project has deviated from the SOW due to timeline impact from the issues noted above with the ongoing clinical hold.

4. Quarterly Financial Expenditures:

Given the ongoing clinical hold, MAPS has - and will continue to minimize direct and administrative costs and be good stewards of the CRA grant. As a result of our review, we have decreased the number of CRO engagement meetings to limit costs during this clinical hold period and we have negotiated reimbursement for medical monitor related fees. Additionally, MAPS is reviewing other cost cutting measures such as reviewing supplies purchasing plans and reviewing contractor assignments.