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15 July 2024

Rigoberto Roca, MD, Division Director
Division of Anesthesia, Analgesia and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: **NDA 209511, SN 0109**
Sponsor: **Innocoll Pharmaceuticals Limited (In receivership) ("Innocoll")**
Product: **XARACOLL® (bupivacaine HCl) Implant**
Subject: **RESPONSE TO PREA NON-COMPLIANCE LETTER**
DEFERRAL EXTENSION REQUESTED

Dear Dr. Roca:

Reference is made to New Drug Application (NDA) 209511 for Xaracoll (bupivacaine HCl) implant submitted on February 2, 2018 (Sequence 0008). The NDA was approved on August 28, 2020, and the approval letter contained postmarketing requirements (PMRs) 3928-1 and 3928-2, which were deferred until 31 May 2024 and 31 August 2023, respectively. These PMRs described randomized, controlled studies to assess Xaracoll following open inguinal hernia repair in children 2 to 17 and less than 2 years of age. Innocoll received notification of non-compliance with PREA in a letter dated 28 May 2024 since PMR 3928 had not been completed yet, nor had an extension to the deferral been requested.

On behalf of the asset owner, Innocoll, Allucent, a contract research organization, is requesting an extension to the deferral for PMR 3928-1 and PMR 3928-2. Please note that by instrument of appointment dated 5 December 2023, (b) (4) the assets of Innocoll (b) (4) in favour of Gurnet Finance SA and which assets include the asset the subject of the aforementioned New Drug Application. The Joint Receivers are the only persons with the requisite authority to make any decisions in relation to the assets to which they stand appointed.

Innocoll is in the final stages of a (b) (4) and it is expected that a supplemental NDA (sNDA) will be submitted in Q4 2024 to expand the Xaracoll indication to include soft tissue surgeries. Innocoll had, prior to the Joint Receivers' appointment in December 2023, previously discussed with FDA that patients with soft tissue disease could be included in the pediatric studies of Xaracoll, and this plan is included in the agreed iPSP notification from FDA dated 23 March 2022. At the time of the agreed iPSP, Innocoll planned to submit an sNDA in (b) (4) to add soft tissue surgeries to the adult indication; however, this submission has been delayed until (b) (4) due to additional time required to prepare the data package supporting the application.

Currently, Study INN-CB-020 has enrolled (b) (4) patients in the 12- to <17-year-old age group and (b) (4) patients in the 6- to <12-year-old-age group. The practice of medicine has evolved to many physicians preferring laparoscopic procedures for repairing inguinal hernias instead of an open laparotomy approach. This

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evolution in the standard of care has led to site closures in Study INN-CB-020, with only one site currently open (see Section 1.13.12 from the most recent annual report). Innocoll is committed to expanding the patient population of this trial to include soft tissue surgeries upon submission of the sNDA [redacted] (b) (4), at which point, it is expected that a substantial improvement in the enrollment rate of Study INN-CB-020 will be seen. Once sufficient data (as described in the agreed iPSP) is available from Study INN-CB-020 to propose a dose for Study INN-CB-021 in subjects <2 years, Innocoll [redacted] (b) (4)) will begin enrollment in the second trial. However, [redacted] (b) (4), Innocoll (acting by the Joint Receivers) makes a commitment to submit a follow-up communication to FDA [redacted] (b) (4) regarding updated milestone dates PMRs 3928-1 and 3928-2.

A signed Form FDA 356h is also enclosed. The size of the electronic files included in this submission is <10 MB. All electronic files were checked for viruses by Windows Defender Antivirus, Product Version 1.415.112.0, 15 July 2024, before submitting via the Electronic Submissions Gateway.

Please note that Innocoll had previously authorized Allucent to interact with the FDA on its behalf. For good order, the Joint Receivers (acting in their capacity as joint receivers and agents of Innocoll) have similarly confirmed that it is in order for Allucent to continue to interact with the FDA on behalf of Innocoll. It is on the basis, however, that all personal liability of the Joint Receivers arising out of or in connection with Innocoll's application for an extension of the deferral (as referred to in this letter) is excluded.

If you have any questions or need additional information, please do not hesitate to contact me directly by phone at 919-361-2286 or by email at joshua.taylor@allucent.com.

Sincerely,

DocuSigned by:
Joshua Taylor
Signer Name: Joshua Taylor
Signing Reason: I approve this document
Signing Time: 15-Jul-2024 | 12:46 PDT
3AEB1D41654D40D4A77935B1DB1EEB8A

Joshua Taylor
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