



Our STN: BL 125668/o

**MID-CYCLE COMMUNICATION
SUMMARY**
July 10, 2018

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Mr. Stanley Ammons
Octapharma USA Inc.
121 River Street, Suite 1201
Hoboken, NJ 07030

Dear Mr. Ammons:

Attached is a copy of the summary of your June 11, 2018, Mid-Cycle Communication Teleconference with Center for Biologics Evaluation and Research (CBER). This memorandum constitutes the official record of the Teleconference. If your understanding of the Teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

Please include a reference to STN BL 125668/o in your future submissions related to your Immune Globulin Subcutaneous (Human) product.

If you have any questions, please contact Edward Thompson at (240) 402-8443.

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Summary

Application number: BL 125668/o
Product name: Immune Globulin Subcutaneous (Human)
Proposed Indication: For treatment of primary immunodeficiency (PID) in adults
Applicant: OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.
Meeting date & time: June 11, 2018 2:30 PM-3:30 PM Eastern Time (US & Canada).
Committee Chair: Michael Kennedy, PhD
RPM: Edward Thompson

FDA Attendees:

Basil Golding, MD, OTAT/DPPT
Michael Kennedy, PhD, OTAT/DPPT/PDB
Edward Thompson, OTAT/DRPM/BII

OCTAPHARMA Pharmazeutika Produktionsges.m.b.H. Attendees:

Barbara Rangetiner, General Manager OPG, Director, International Drug Regulatory Affairs
Xenia Serro, International Drug Regulatory Affairs Manager
Stanley Ammons, Local Agent / Sr. Director, Government Policy & Corporate Compliance, Octapharma USA Inc.
Wolfgang Toeglhofer, Vice President Clinical R&D Immunology & Critical Care
Eva Turpel-Kantor, Deputy Medical Director, Immunotherapy

Agenda:

To discuss the progress of the review.

Discussion Summary:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.

The review team has not identified any significant issues/major deficiencies at this time

2. Information regarding major safety concerns.

The review team has not identified any major safety concerns at this time.

3. Preliminary Review Committee thinking regarding risk management.

The review team has no comments regarding risk management at this time.

4. Any information requests sent and responses not received.

We sent a request to submit updated bioanalytical method validation report for analytes in your clinical study SCGAM-01 on May 29, 2018, for which we requested a response by June 12, 2018.

We sent a request for modifications to the Lot Release protocol on May 31, 2018, for which we requested a response by June 11, 2018.

We sent a request for Chemistry, Manufacturing, and Controls (CMC) data on May 31, 2018, for which we requested a response by June 18, 2018.

5. Any new information requests to be communicated.

We are preparing an information request that would be submitted by mid-June (Randa Melhem) and will request a response in 2-weeks.

We are also drafting an information request for you to submit up to 10 suffix names per the following guidance:

<https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>

We anticipate sending this request to you before June 15, 2018 with a response from you in 2-weeks.

6. Proposed date for the Late-Cycle meeting (LCM).

The LCM between you and the review committee is currently scheduled for September 6, 2018, and the LCM Materials will be sent on or before August 24, 2018.

If these timelines change, we will communicate updates to you during the course of the review.

7. Updates regarding plans for the AC meeting.

There are no plans to present this Biologics License Application (BLA) to Blood Products Advisory Committee (BPAC) at this time.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

Tentative Labeling Target Date: November 29, 2018

Tentative PMC Target Date: November 29, 2018

9. Additional comments.

Clinical:

We note that the draft package insert (PI) recommends using a dosage correction factor of (b) (4) for calculating the IGSC dose, whereas a correction factor of 1.50

was used in the Phase 3 trial. The dosing regimen recommended in the draft PI should match that used in the Phase 3 study.

We note that the draft PI recommends an inter-dosing interval that varies from daily up to every (b) (4) [REDACTED], whereas only a weekly dosing interval for the investigational IGSC product was used in the Phase 3 study. The dosage regimen recommended in the draft PI should match that used in the Phase 3 study.

End