

## **FILING MEETING 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:** Friday, January 19, 2018, 3:00 PM-4:00 PM  
**Committee Chair:** Michael Kennedy, PhD  
**Meeting Recorder:** Edward Thompson

### **Background:**

The applicant submitted this BLA for an immune globulin (human) product for subcutaneous administration, formulated in a liquid presentation. They request to use this product for the treatment of primary immunodeficiency. The development of this product is based on the manufacturing process of the licensed products Octagam 5% and 10% (STN 125062), immunoglobulins intravenous (human). Octagam 5% was approved in the United States on May 21, 2004 (STN 125062). Octagam 10% was approved in the United States on July 11, 2014 (STN 125062/234).

### **Review Team**

Chair – Michael Kennedy  
RPM – Edward Thompson  
Clinical Reviewer – Yeowon Kim  
Clinical Pharmacologist – Xiaofei Wang  
CMC Reviewer – Margaret Norton  
CMC Reviewer – Nancy Eller  
CMC Reviewer – Lu Deng  
Pharmacology/Toxicology Reviewer – Evi Struble  
OCBQ DMPQ RPM – Amanda Trayer  
OCBQ DMPQ CMC Facility – Randa Melhem  
OCBQ DMPQ Team Lead – Anthony Lorenzo  
Statistical Reviewer – Boris Zaslavsky  
Epidemiologist Reviewer – Shaokui Wei  
OCBQ APLB Reviewer – Alpita Popat  
OCBQ BIMO Reviewer – Erin McDowell  
DBSQC Reviewers - Hsiaoling (Charlene) Wang  
DBSQC Reviewers - Leslyn Aaron  
DBSQC Reviewers - Jing Lin  
DBSQC Reviewers - Simleen Kaur  
DBSQC Reviewers - Varsha Garnepudi

### **Attendees:**

Michael Kennedy  
Lu Deng  
Edward Thompson  
Nancy Eller

Yeowon Kim  
Randa Melhem  
Boris Zaslavsky  
Erin McDowell  
Varsha Garnepudi  
Simleen Kaur  
Tejashri Purohit-Sheth  
Mahmood Farshid  
Rachael Anatol

Shari Targum  
Shaokui Wei  
Renee Rees  
Alpita Popat  
Leslyn Aaron  
Xiaofei Wang  
Ilan Irony  
Ramani Sista  
Kimberly Benton

## **Regulatory Conclusions / Deficiencies**

- 1. Does the application, on its face, appear to be suitable for filing or is the application unsuitable for filing and will require a RTF letter?**

All review team members present for the filing meeting consider the application fileable.

- 2. If fileable, list any substantive deficiencies or issues that have significant impact on the ability to complete the review or approve the application:**

There are issues with the datasets which may impact the ability to complete the clinical and statistical review of the BLA. The CDISC data quality review found three issues with the exposure data that will require additional information from the sponsor: 1) A majority of the treatments occurred before the date/time of the first study treatment, 2) 40% of exposure records is missing timing information, and 3) there are an excessive number of total exposure records (i.e. 24,824) in comparison to the number of exposures one would expect during the study (i.e. if 61 subjects each received 64 infusions of SCIG, one would expect 3,904 exposure records). An information request was sent to the sponsor on 05 February 2018.

- 3. If RTF, list any substantive deficiencies or issues that would make this application unsuitable for filing:**

NA

## **Filing Meeting Discussion, IF FILED:**

- 4. Indicate any comments on the status of the proprietary name review (PNR).**

Review of the PNR will be routed to the RPM for team notification and acceptance.

- 5. Indicate whether the product would be subject to lot release, surveillance, or exempt from lot release. Verify sample availability.**

Discussion premature. More discussion at the mid cycle meeting by DBSQC.

- 6. Confirm review schedule of this application. [Standard Review, Priority Review, or Expedited Review]**

Standard Review

- 7. Indicate the decision regarding the need for an Advisory Committee.**

None

- 8. Indicate whether the submission triggers PREA; if yes, a PeRC meeting is needed.**

PREA is triggered; Discussion on PeRC scheduling at the mid cycle meeting.

- 9. Is a comprehensive and readily located list of all clinical sites included or referenced in the application?**

Yes

- 10. Is a comprehensive and readily located list of all manufacturing facilities included or referenced in the application?**

Yes

- 11. Indicate any updates since the First Committee Meeting on pre-license inspection, pre-approval inspection, or BIMO sites requiring inspections (Is the establishment(s) ready for inspection?)**

BIMO inspections will be issued, all other inspections will be waived

- 12. If the application is affected by the Application Integrity Policy (AIP), has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance?**

No

- 13. Is the product an Original Biological Product or a New Molecular Entity (NME) for an NDA?**

No

**FOR APPLICATIONS IN THE PDUFA PROGRAM (NME NDAs/Original BLAs), IF FILED**

- 14. Confirm that any late submission components were submitted within 30 days. List any late submission components that arrived after 30 days.**

No

- 15. Was the application otherwise complete upon submission, including those applications where there were no agreements regarding late submission components?**

Yes

**Administrative Details, IF FILED:**

- 16. Review the Milestone Schedule and indicate if there are any issues with the schedule. Note: This is a confirmation to capture any changes made since the First Committee Meeting.**

No issues.