Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

To:	BLA 125062/674
From:	Evi Struble, Ph.D., Research Pharmacology, PDB, DPPT, OTAT Evi B. Struble -S Digitally signed by Evi B. Struble -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Evi B. Struble -S, 0.9.2342.19200300.100.1.1=001356892 Date: 2021.06.23 14:34:55 -04'00'
Cross-reference:	IND 16925
Through:	Dorothy Scott, M.D., Branch Chief, PDB, DPPT, OTAT Dorothy E. Scott -S Digitally signed by Dorothy E. Scott -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000083123, cn=Dorothy E. Scott -S Date: 2021.06.29 11:23:35 -04'00'
CC:	Adriane Fisher, RPM, OTAT/DRPM
Applicant:	OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.
Product:	Octagam 10%, Immune Globulin Intravenous (Human) for Dermatomyositis
Subject:	Preclinical Pharm-Tox Review

Contents

Introduction

Octagam 10% is an Immune Globulin Intravenous (Human) approved for the indication of chronic immune thrombocytopenia purpura (ITP). In this supplemental BLA application, the sponsor submitted data to support its use for the treatment of dermatomyositis (DM) at the proposed dose of 2 g/kg divided in equal doses given over 2-5 consecutive days every 4 weeks.

The submission contains data from clinical trial GAM10-08 performed under IND 16925 to assess efficacy, safety and tolerability of Octagam 10% in DM patients.

Preclinical Pharmacology and Toxicology

No new pharmacology/toxicology data was submitted in this application. The product has been approved for the ITP indication at a dose of 1.0 g/kg daily, for two consecutive days. A similar product, Octagam 5%, with the same formulation but a lower IgG concentration, has been approved since 2004 for primary humoral immunodeficiency (PI) indication. The recommended dose for Octagam 5% is up to 600 mg/kg

given every 3-4 weeks. The existing safety database on the use of Octagam 5% and 10% in clinical subjects supports the use of this product in DM indication. No additional pharmacology/toxicology studies are needed.

Recommendation

Approval is recommended from the pharmacology and toxicology discipline perspective.