Our STN: BL 125668/158

SUPPLEMENT APPROVAL
PMR FULFILLED
October 22, 2021

OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.
Attention: Stanley Ammons
17 West Century Road
Paramus, NJ 07652

Dear Mr. Ammons:

We have approved your request submitted and received December 23, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Immune Globulin Subcutaneous (Human)-hipp, 16.5% (Cutaquig) to:

1. Submit the Final Study Report for the Required Pediatric Assessment under Pediatric Research Equity Act (PREA) Postmarketing Requirement (PMR) #1 associated with the BLA approval letter dated December 12, 2018, for STN BL 125668/0, and

2. Update the prescribing information and expand the use of Cutaquig to pediatric patients ages two to < 17 years of age for the treatment of primary humoral immunodeficiency.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: 01888484 and 02627300.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft package insert labeling submitted under amendment 8 on October 21, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL)

format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on October 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement PMR #1 identified in the December 12, 2018 approval letter for BLA STN BL 125668/0 for Immune Globulin Subcutaneous (Human)-hipp. The requirement addressed in this submission is as follows:

1. Deferred pediatric study (protocol SCGAM-01) under PREA for the treatment of primary humoral immunodeficiency in pediatric patients ages two to < 17 years of age. The study will provide pharmacokinetic data for at least two

subjects ages two to < 6 years, at least six subjects ages six to < 12 years, and at least four subjects ages 12 to < 17 years of age, as well as safety and efficacy data for at least four subjects ages two to < 6 years, at least 10 subjects ages six to < 12 years, and at least six subjects ages 12 to < 17 years of age. The final report will compare efficacy and safety between pediatric age cohorts and between pediatric and adult subjects included in the study.

Final Protocol Submission: January 31, 2019

Study Completion Date: August 31, 2020

Final Report Submission: December 31, 2020

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research