CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761270Orig1s000

PRODUCT QUALITY REVIEW(S)

Recommendation: Approval

BLA 761270 Number:
Assessment Number:1
Assessment Date: September 08, 2022

Drug Name/Dosage Form	tremelimumab-actl; MEDI 1123; Imjudo™; Injection
Strength/Potency	20 mg/mL; 25 mg/vial and 300 mg/vial In vitro cell-based IL-2 reporter assay
Route of Administration	Intravenous infusion
Rx/OTC dispensed	RX
Indication	Tremelimumab in combination with durvalumab (FDA approved drug product) and platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
Applicant/Sponsor	AstraZeneca AB, Sweden
US agent, if applicable	AstraZeneca Pharmaceuticals LP

Product Overview:

Tremelimumab (Imjudo)) is a fully human immunoglobulin gamma-2 (IgG2) monoclonal antibody (mAb) engineered to bind to cytotoxic T lymphocyte-associated antigen-4 (CTLA-4; CD152), a cell surface receptor expressed on activated T cells. Upon T-cell activation, CTLA-4 expression is upregulated and acts to dampen immune responses, modulating and eventually switching off T-cell activation. The natural ligands for CTLA-4 are CD80 [B7.1] and CD86 [B7.2], which are present on antigen-presenting cells (APCs). Binding of CTLA-4 to CD80/CD86 functions to limit T-cell activation, primarily by competing with CD28 for access to CD80/CD86. Tremelimumab is manufactured in NS0 cells (b) (4)
Tremelimumab is supplied at a 20 mg/mL strength as a 25 mg/vial and 300 mg/vial for intravenous infusion. Tremelimumab has one N-linked glycosylation site at Asn 301 in the Fc region on each of the two heavy chains in the consensus sequence Asn-Ser-Thr (NST).

Quality Assessment Team:

Discipline	Assessor	Branch/Division
Drug Substance	Xu Di	OBP/Division of Biotechnology Review and Research (DBRR) III
Drug Product	Xu Di	OBP/DBRRIII
Immunogenicity	Xu Di	OBP/DBRRIII
Labeling	Vicky Borders-Hemphill	OBP Labeling

Microbiology/Facility	Maria Scott (DS)/ Virginia Carroll TL Zonglin Hu (DP) /Madushini Dharmasena TL	OPMA/DBM Branch 2
Application Team Lead	Ram Sihag	OBP/DBRRIII
Application Tertiary Reviewer	Frances Namuswe	OBP/DBRRIII
RPBM	Grafton Adams	OPRO

Multidisciplinary Assessment Team:

Discipline	Assessor	Office/Division
RPM	Idara Ojofeitimi	CDER/DROOD
Cross-disciplinary Team Lead	Drezner Nicole	CDER/OND/DO2
Medical Officer	Erica Nakajima	CDER/OND/OOD/DO2
Nonclinical	Melissa Pegues/Claudia Miller (Team Leader)	CDER/OND/DHOT
Pharmacometrics	Ye Yuan/Liang Li (Team Leader)	CDER/OND/DPM
Clinical Pharmacology	Yue Xiang/Hong Zhao (Team Leader)	CDER/OTS/OCP/DCPI
Statistics	Arup Sinha/Pallavi Mishra-Kalyani (Team Leader)	CDER/OTS/DBV

1. Names:

a. Proprietary Name: Imjudo™
b. Trade Name: Imjudo™
c. Non-Proprietary Name/USAN: tremelimumab-actl
d. CAS Name: 745013-59-6
f. INN Name: tremelimumab-actl
g. Compendial Name: not assigned
h. OBP systematic name: MAB HUMAN (IGG2) ANTI P16410 (CTLA4_HUMAN) [MEDI1123]

Submissions Assessed:

Submission:	Date Received:	Review Completed (yes or no)
BLA 761270/1 (original BLA)	November 15, 2021	Yes
BLA 761270/15 (response to information request #1)	May 6, 2022	Yes
BLA 761270/17 (response to information request #2)	May 23, 2022	Yes
BLA 761270/22 (response to information request #3)	June 22, 2022	Yes
BLA 761270/23 (response to	July 6, 2022	Yes

information request #4)		
BLA 761270/28 (response to information request #5)	July 25, 2022	Yes
BLA 761270/29 (response to information request #6)	July 29, 2022	Yes
BLA 761270/31 (response to information request #7)	August 9, 2022	Yes
BLA 761270/32 (response to information request #6 additional IR response)	August 12, 2022	Yes
BLA 761270/36 (response to information request #8)	August 22, 2022	Yes
BLA 761270/39 (response to information request #9)	August 29, 2022	Yes

Quality Assessment Data Sheet:

1. Legal Basis for Submission: 351(a)
2. Related/Supporting Documents:

A. DMFs:

DMF#	DMF Holder	Item Referenced	Letter of Cross-Reference	Comments (status)
(b) (4)			Yes	Adequate information provided in the BLA.
			Yes	Adequate information provided in the BLA.
			Yes	Adequate information provided in the BLA.
			Yes	Adequate information provided in the BLA

B. Other documents: IND, Referenced Listed Drug (RLD), or sister application.

IND 124702, BLA 761289 and BLA 761069 (Durvalumab)

Communication/Document:	Date:
Information Request #1	April 28, 2022
Information Request #2	May 9, 2022
Information Request #3	June 14, 2022
Information Request #4	June 28, 2022
Information Request #5	July 18, 2022
Information Request #6	July 22, 2022
Information Request #7	August 2, 2022
Information Request #8	August 19, 2022
Information Request #9	August 23, 2022

3. Consults: None

4. Environmental Assessment of Claim of Categorical Exclusion:

AstraZeneca requested a categorical exclusion from the requirement to prepare an environmental assessment in accordance with 21 CFR 25.31(c) and indicated that there are no extraordinary circumstances that might significantly affect the quality of the human environment. The claim of categorical exemption is acceptable because tremelimumab is a protein product that occurs naturally and will be broken down in the environment. Therefore, tremelimumab is not expected to significantly impact the environment

Executive Summary:

I. Recommendations:

A. Recommendation and Conclusion on Approvability:

Recommendation:

The Office of Biotechnology Products, OPQ, CDER, recommends approval of BLA 761270 for tremelimumab (Imjudo) manufactured by (b) (4) (drug substance) and (b) (4) (drug product), for AstraZeneca Pharmaceutical. The data submitted in this application are adequate to support the conclusion that the manufacture of tremelimumab is well-controlled and leads to a product that is pure and potent. It is recommended that this product be approved for human use under conditions specified in the package insert.

B. Approval Action Letter Language:

- Manufacturing location:
  - Drug Substance:

    (b) (4)

  - Drug Product:

    (b) (4)

    AstraZeneca AB (Labeling, storage, and secondary packaging)
    Forskargatan-18
    151 85 Södertälje, Sweden
    FEI: 3002806411

- Fill size and dosage form:
  i). Injection: 25 mg/1.25 mL (20 mg/mL) solution in a single-dose vial.
  ii) Injection: 300 mg/15 mL (20 mg/mL) solution in a single-dose vial.

- Dating period:
  - Drug Product: 48 months at 2-8°C

- Drug Substance: A total of (b) (4) months of DS shelf life is recommended, (b) (4)
- Intermediate Substance: N/A
- Stability:
  - For stability protocols: None

- Exempt from lot release:
  - Yes
  - Rationale, if exempted: Tremelimumab is exempted from lot release per FR 95-29960.

C. Benefit/Risk Considerations:

The tremelimumab manufacturing process and overall control strategy are sufficient to ensure consistent manufacture of a drug product that is safe and effective. All proposed manufacturing and testing facilities are acceptable based on their current cGMP compliance status and recent on-site inspection coverage. The approval of tremelimumab will increase treatment options for patients currently undergoing therapy for metastatic NSCLC.

D. Recommendation on Phase 4 (Post-Marketing) Commitments, Requirements, Agreements, and/or Risk Management Steps, if approvable:

1. PMC- 4333-4 To perform a shipping validation study under real time shipping conditions (i.e. temperature, mode of transport, shipping duration, and shipping containers and packing representative of the minimum and maximum load) using a representative commercial tremelimumab drug product lot in the final commercial container closure and packaging systems to evaluate the ability of the shipping containers to maintain the recommended temperature and to evaluate the impact of shipping from the AstraZeneca Sweden labeling and packaging site to the US Distribution Center on the physical integrity and product quality of tremelimumab drug product. The shipping validation data will be submitted in accordance with 21 CFR 601.12.

Final Report Submission: 12/31/2023

2. PMC- 4333-5 Implement (b) (4) monitoring (b) (4) validated by the microbial retention study.

Final Report Submission: 12/31/2023

II. Summary of Quality Assessments:

The tremelimumab product quality information supports the approval of this BLA. The tremelimumab drug substance (DS) and drug product (DP) are well characterized and free of adventitious infectious agents. The manufacturing process control parameters used in the manufacture of DS and DP were

adequately validated or are supported by process characterization studies or platform knowledge/prior experience from other monoclonal antibodies manufactured at the DS and DP manufacturing sites. The process validation results demonstrate that the proposed commercial manufacturing process can consistently produce a pure and potent product. The proposed lot release and stability specifications of DS and DP are supported by clinical and manufacturing experience. Overall, the control strategy for tremelimumab is adequate.

Two commercial DP presentations are proposed: 25 mg/vial and 300 mg/vial. A 400 mg/vial presentation was used during the clinical studies. The 25 mg/vial, 300 mg/vial and 400 mg/vial presentations were demonstrated to be comparable. The Applicant provided 48 months of real time stability data for 8 DP lots (3 lots for 25 mg/vial and 5 lots for 400 mg/vial) manufactured at commercial scale to support the proposed 48 months expiry for tremelimumab DP stored at 2 -8 °C. The proposed DP expiry is adequately supported. The Applicant provided 48- and 36- months of real time stability data for DS (b) (4) . Based on the totality of the available DS and DP stability data, a total of (b) (4) months of DS shelf life will be approved, (b) (4)

No significant deficiencies were identified during the review of BLA 761270 that preclude approval of this application from OPQ's perspective. The adequacy of the immunogenicity assays and a risk assessment of the immunogenicity profile of tremelimumab was performed. All the method validation results met the appropriately predefined acceptance criteria. The immunogenicity assay performance results (e.g., ADA and Nab incidences) from the clinical studies demonstrated that both ADA and Nab assays were suitable for their intended use.

A. CQA Identification, Risk and Lifecycle Knowledge Management

Table 1 below is a summary of critical quality attributes and the associated control strategies for attributes that are relevant to both Drug Substance and Drug Product. For additional information, see the primary reviews, including the Drug Substance and Drug Product Quality Review by OBP/DBRRIII (https://panorama.fda.gov/document/view?ID=62ff9b0e001c930e5affb1a39e250c21) and the Drug Substance Microbiology Review and the Drug Product Microbiology Review by OPMA (https://panorama.fda.gov/document/view?ID=62f592af00760bb299848bea55e8bc63 and https://panorama.fda.gov/document/view?ID=630f801f00039817fe650c5083b12511).

Table 1: Active Pharmaceutical Ingredient CQA Identification, Risk and Lifecycle Knowledge Management

CQA (type)	Risk	Origin	Control Strategy	Other
Aggregates (Product related impurity)	Immunogenicity	(b) (4) on stability	(b) (4)	n/a
Fragments (product related impurity and substance)	Immunogenicity, reducing potency, safety and efficacy failure	(b) (4) on stability		n/a

			(b) (4)	
Disulfide bond modifications (product related impurity)	Immunogenicity	(b) (4)		n/a
Fc glycosylation (high mannose) (product related impurity)	Immunogenicity, PK	(b) (4)		n/a
Deamidation (acidic variants, light chain Asn-30) (product related impurity)	Reducing potency	(b) (4) DS and DP storage		n/a
Fc Oxidation (Met-256 and Met-432) (product related impurity)	Reducing potency	(b) (4) DS and DP storage		n/a
CDR Oxidation (Heavy chain Trp-52) (product related impurity)	Potency	(b) (4) DS and DP storage		n/a
Primary Sequence Variants	Potency, immunogenicity, PK	Cell line		n/a
Higher order structure	Potency, immunogenicity, PK	Cell line		n/a
Potency	Efficacy failure	Intrinsic to molecule, in-process and on stability		n/a
Identity	safety and efficacy failure	Intrinsic to molecule		n/a
Total protein	Inaccurate dosing	Formulation		n/a

B. Drug Substance Quality Summary

CQA Identification, Risk, and Lifecycle Knowledge Management

A summary of the critical quality attributes and the control strategy that is relevant specifically to the Drug Substance is shown below in Table 2.

Table 2: Drug Substance CQA Process Risk Identification and Lifecycle Knowledge Management.

CQA (type)	Risk	Origin	Control Strategy	Other
Appearance (clarity, color)	Product stability	Formulation and storage	(b) (4)	n/a
pH	Product stability	Formulation and storage		n/a
Leachable impurities	Safety and product stability	Process-related impurities, and DS container closure system		n/a

			(b) (4)	
Host Cell DNA	Immunogenicity and Safety	(b) (4)		n/a
Host Cell Protein	Immunogenicity	(b) (4)		n/a
(b) (4)	Immunogenicity	(b) (4)		n/a
(b) (4)	Product stability	Formulation		n/a
	Product stability	formulation		n/a
Bioburden	Safety, purity, efficacy	Contamination during manufacturing process		n/a
Endotoxin	Safety and purity	Endotoxin can be introduced by raw materials and contamination during manufacturing process		n/a
Mycoplasma	Safety	Contamination during manufacturing process		n/a
Adventitious Viruses	Safety	Contamination during manufacturing process		

n/a Not applicable

- Description:

  Tremelimumab drug substance is a fully human monoclonal antibody from the immunoglobulin (Ig) G2a isotype targeted against Cytotoxic T Lymphocyte-associated Antigen 4 (CTLA-4 or CD152) being developed to treat cancer. CTLA-4 is a cell surface receptor expressed on activated T cells. Tremelimumab consists of two heavy chains and two light chains covalently connected with 6 inter-chain disulfide bonds. Tremelimumab has one N-linked glycosylation site at Asn (N) 301 in the Fc region on each of the two heavy chains in the consensus sequence Asn-Ser-Thr (NST).

- Mechanism of Action (MoA):

  The MOA of tremelimumab is to block CTLA-4 from binding to B7 ligands (CD80 and CD86) on antigen-presenting cells. This blockade results in enhanced T cell mediated immune response (e.g., T cell activation, proliferation, and lymphocyte infiltration into tumors) to kill the tumor cells.

- Potency Assay:
  The potency of tremelimumab is determined using an IL-2 reporter potency assay, which is a cell-based assay using Jurkat cells expressing CTLA-4 and an IL-2-promoter driven lucifierase, and Raji cells expressing B7 ligands. The potency assay was

established based on the ability of tremelimumab to block the CTLA-4-mediated inhibitory signal during T cell activation by blocking CTLA-4 from binding to B7 ligand on the B lymphocytes. The T cell activation is correlated to activation of the IL-2 transcription factor, leading to the expression of luciferase. The generated luciferase measured by a luminometer is proportional to the T cell activity after reacting with luciferase substrate. After confirming parallelism, a constrained 4PL curve fit is performed, and the relative potency of the sample is determined by dividing the EC50 of RS by the EC50 of samples.

- Reference Materials:

(b) (4)

The qualification of reference standards is acceptable.

- Critical starting materials or intermediates:

Tremelimumab is produced in NS0 cells, (b) (4) A two-tiered cell banking system comprising of the Master Cell Bank (MCB) and a Working Cell Bank (WCB), with appropriate characterization, stability testing program, and storage conditions, has been implemented to ensure consistent manufacture of the product.

- Manufacturing process summary:

The manufacturing process of tremelimumab DS consists of (b) (4)

(b) (4)

From a microbiological perspective, the process is under adequate microbial control.

(b) (4)

All the process validation results for process parameters, process outputs, and additional quality attributes met the predefined acceptance criteria, which were within process characterization ranges or based on prior knowledge. All the available results from commercial scale DS lots met the acceptance criteria in terms of step yield, chromatogram profile, and product quality.

- Container closure:

(b) (4)

- Dating period and storage conditions:
A total of (b) (4) months of DS shelf life is recommended, (b) (4)

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Note: The Applicant had proposed (b) (4)

C. Drug Product Quality Summary:

A summary of the identification, risk, and lifecycle knowledge management for drug product CQAs that derive from the drug product manufacturing process and general drug product attributes is provided below in Table 3.

Table 3: Drug Product CQA Identification, Risk, and Lifecycle Management

CQA (type)	Risk	Origin	Control Strategy	Other

Sterility	Infections in patients, product stability	Accidental during fill, container closure failure	(b) (4)	n/a
Endotoxin	Adverse reactions in patients, DP failure	Accidental throughout process		n/a
Container Closure Integrity (CCI)	Infections in patients, product stability	container closure failure		n/a
Appearance (clarity, color)	Product stability	Formulation and storage		n/a
Visible particles	Patient safety and product stability	Formulation		n/a
Osmolarity	Product stability, patient discomfort	Formulation		n/a
pH	Product stability and DP failure	Formulation		n/a
Extractable Volume	Inaccurate dosing	Filling		n/a
Sub-visible particles	Product stability	Formulation		n/a
Leachable impurities	Safety	Process-related impurities, and DP container closure system		n/a
Polysorbate 80	Product stability	Formulation		n/a

- Potency and Strength: 25 mg/vial and 300 mg/vial, protein concentration is 20 mg/mL

  The in vitro cell-based assay is used to measure the potency of tremelimumab DS and DP for release and stability testing. The potency assay is discussed above in DS section. The strength of the DP is 20 mg/mL. Tremelimumab is supplied as a 25 mg/vial and 300 mg/vial for intravenous infusion.

- Summary of Product Design:

Tremelimumab DP is a sterile, preservative-free solution intended for intravenous infusion after dilution. DP has two presentations: 25 mg/1.25 mL vial and 300 mg/15 mL vial. Each presentation contains 20 mg/mL tremelimumab in (b) (4) mM histidine/histidine-HCl monohydrate, (b) (4) mM trehalose (b) (4) mM disodium edetate (b) (4) % (w/v) polysorbate 80, pH 5.5.

The 25 mg/vial DP presentation is a single dose vial that contains a label claim of 25 mg of tremelimumab in a 1.25 mL volume (b) (4) mL target fill volume (b) (4)). The 300 mg/vial DP presentation is a single-dose vial that contains a label claim of 300 mg of tremelimumab in a 15 mL volume ((b) (4) mL target fill volume (b) (4)).

- List of Excipients: Excipients include 20 mM histidine/histidine-HCl monohydrate, (b) (4) mM trehalose (b) (4) mM disodium edetate (b) (4) % (w/v) polysorbate 80, pH 5.5.

- Reference Materials: The reference materials used for the DP are the same as the reference materials used for DS.

- Manufacturing process summary:
  The manufacturing process of tremelimumab DP involves (b) (4) Bioburden and endotoxin are tested during manufacture and sterility and endotoxin are tested at DP release. Container closure integrity testing is performed during the stability program.

- Container closure:
  The 25 mg/vial presentation is stored in a (b) (4) Glass vial with a grey (b) (4) l elastomer (b) (4) stopper and a flip-off aluminum seal.

  The 300 mg/vial presentation is stored in a (b) (4) Glass vial with a grey (b) (4) elastomer (b) (4) stopper and a flip-off aluminum seal.

- Dating period and storage conditions: A total of 48 months at 2-8°C is given for both 25 mg/vial and 300 mg/vial presentations.

- List of co-package components, if applicable: None.

D. Biopharmaceutics Considerations: N/A
E. Novel Approaches/Precedents: No
F. Any Special Product Quality Labeling Recommendations: No

G. Establishment Information:

Overall Recommendation:					
DRUG SUBSTANCE					
Function	Site Information	DUNS/FEI Number	Preliminary Assessment	Inspectional Observations	Final Recommendation
• Manufacture, testing and storage of working cell banks • Manufacture of drug substance • Release and stability testing of drug substance		(b) (4)	n/a	n/a	The PLI of the DS manufacturing site was waived based on the compliant GMP status.
Bioassay testing for release and stability of Drug Substance	AstraZeneca AB Gärtunavägen 151 85 Södertälje Sweden	FEI: 3003342394 DUNS:631892705	n/a	n/a	Approve - Based on Previous History
Master Cell Bank storage		(b) (4)	n/a	n/a	Approve - Based on Previous History
Master Cell Bank storage			n/a	n/a	Approve - Based on Previous History
Working Cell Bank storage			n/a	n/a	Approve - Based on Previous History
DRUG PRODUCT					
Function	Site Information	DUNS/FEI Number	Preliminary Assessment	Inspectional Observations	Final Recommendation
Drug Product manufacture Release and stability testing [a]		(b) (4)	The DP manufacturing site was inspected by FDA inspectors (b) (4) and a 3-item Form FDA 483 was issued, and it is recommended that the	(b) (4)	Acceptable

			inspection be classified as VAI.	(b) (4)	
Release and stability testing [a]	(b) (4)		n/a	n/a	Approve - Based on Previous History
Release and stability testing [a]			n/a	n/a	Approve - Based on Previous History
Stability testing [b] Warehousing			n/a	n/a	Approve - Based on Previous History
Stability testing			n/a	n/a	Approve - Based on Previous History

	(b) (4)				
Release and stability testing [c]	AstraZeneca AB Gärtunavägen 151 85 Södertälje Sweden	FEI: 3003342394 DUNS: 631892705	n/a	n/a	Approve - Based on Previous History
Labeling, storage, and secondary packaging	AstraZeneca AB Forskargatan-18 151 85 Södertälje Sweden	FEI: 3002806411 DUNS:353951254	n/a	n/a	Approve - Based on Previous History

a Includes release testing (appearance, extractable volume, sterility, and endotoxin) and stability testing (appearance (visible particles), color, clarity, and sterility)
b Physicochemical testing (container closure integrity)
c Bioassay and all other testing not performed by (b) (4)
n/a not applicable

H. Facilities: OPQ recommended that the pre-license inspections (PLI) for the drug substance (DS) manufacturing site at (b) (4) be waived based on good compliance history and acceptable current GMP status.

The PLI for the drug product (DP) manufacturing facility at (b) (4) was conducted (b) (4) by OPMA assessors Zonglin Hu and Wayne Seifert. The inspection was system based and covered Quality, Facilities and Equipment, Production, Laboratory Control and Materials. At the conclusion of PLI, a Form 483 citation with a recommendation of VAI (Voluntary Action Indicated) was issued. Also, the GMP compliance of the facility was acceptable. The overall recommendation of OPQ for the DS and DP manufacturing facilities is acceptable.

I. Lifecycle Knowledge Management:

i. Protocols approved:

a. Drug Substance

(b) (4)

b. Drug product

8. (b) (4) Testing Protocol for 300 mg/vial presentation

c. Both Drug Substance and Drug Product

9. DS and DP annual post approval stability protocols (Tables 1and 2 for DS, Table 1for DP).
10. Comparability Protocol - New Product Introductions (this is not the new (b) (4) protocol. This is a protocol to introduce new products at DS manufacturing site (b) (4) 2.R Reginal Information)

ii. Outstanding review issues/residual risk: None

iii. Future inspection points to consider:

(b) (4)

Durvalumab

Durvalumab is an FDA approved product under BLA 761069. The Sponsor cross-references BLA 761069 for durvalumab and a letter of authorization to cross reference BLA 761069 was provided. There are no outstanding issues in BLA 761069. Under BLA 761270 and BLA 761289, the proposed dosing for durvalumab is within the range described in BLA 761069 labeling. Therefore, the maximum allowable endotoxin and host cell DNA exposure are within acceptable limits. Tremelimumab and durvalumab will be administered separately over a period of one hour for each product. Therefore, the maximum allowable endotoxin exposure should not exceed the acceptable limits. Durvalumab will be prepared, stored and administered according to its labeling in BLA 761069, and its use is not expected to significantly impact the environment. Refer to the durvalumab BLA for the CMC review (https://panorama.fda.gov/document/view?ID=58cbecae01aa87e53d46ab0939ee4a76).

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III Review documents related to this Executive Summary:

1. DS and DP product quality review memo dated August 19, 2022, by Dr. Xu Di

https://panorama.fda.gov/document/view?ID=62ff9b0e001c930e5affb1a39e250c21

2. Product quality microbiology/facility review memo in panorama dated September 07, 2022, by Dr. Maria Scott

https://panorama.fda.gov/document/view?ID=630f801f00039817fe650c5083b12511

3. Product quality microbiology/facility assessment review memo in panorama dated September 08, 2022, by Dr. Zhongli Hu

https://panorama.fda.gov/document/view?ID=62f591b200760ad951379b35be97c1d8

4. Establishment inspection report for drug product by Zonglin Hu, Ph.D. and Wayne Seifert (OPQ/OPMA/DBM) will be available in CMS.

5. Review memo for Durvalumab (BLA 761069) in panorama dated March 17, 2017, by Dr. Howard Anderson

https://panorama.fda.gov/document/view?ID=58cbecae01aa87e53d46ab0939ee4a76

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