Approval Date: January 31, 2020

Product: AUDENZ

Proper Name: Influenza A (H5N1) Monovalent Vaccine, Adjuvanted

Manufacturer: Seqirus Inc.

Indication:

- AUDENZ is a vaccine indicated for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine.
- AUDENZ is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.

Description: AUDENZ, a sterile injectable emulsion for intramuscular use, is an inactivated, monovalent, subunit influenza vaccine prepared from virus propagated in Madin Darby Canine Kidney (MDCK) cells, a continuous cell line.

BLA: 125692

Regulatory Milestone:

Fast Track designation was granted in December 2015. At a Type C meeting between the Center for Biologics Evaluation and Research (CBER) and Novartis Vaccines on May 7, 2014, it was agreed that development of the pandemic H5N1. On June 21, 2018, CBER held a pre-BLA meeting with Seqirus to discuss the manufacturing, pre-clinical and clinical information to be included in the BLA submission for the Audenz vaccine. Seqirus indicated that the plans had

changed since the May 7, 2014, Type C meeting and the BLA would include H5N1 drug substance data for product made by Process 3.0 to be consistent with the Flucelvax current manufacturing Process 3.0 licensed on July 27, 2018 (STN 125408/274). On February 1, 2019, CBER received the final submission of the rolling BLA for Audenz, which was assigned the STN 125692. The PDUFA Goal Date is February 1, 2020.

PDUFA Goal Date: February 1, 2020

Package Insert: Package Insert - AUDENZ

Summary Basis for Regulatory Approval: January 31, 2020 Summary Basis for Regulatory Action - AUDENZ

European Public Assessment Report: No data

Advisory Committee:

An Advisory Committee meeting was not held for Audenz since relevant issues regarding licensure of pandemic vaccines were discussed previously at Vaccines and Related Biological Products Advisory Committee (VRBPAC) meetings held on February 29, 2012, and November 14, 2012; and because our review of information submitted in the BLA did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

Safety:

Potential risks identified in the Applicant's Pharmacovigilance Plan (PVP) include uncommon or rare AEs associated with other influenza vaccines: convulsion, neuritis, encephalitis,

vasculitis, Guillain Barre Syndrome (GBS), demyelination, Bell's palsy, syncope and hypersensitivity reactions.

NCT Numbers:

- NCT02612909
- NCT02171819

EudraCT Numbers: No data

Publications:

- Duong, T. N., Thiem, V. D., Anh, D. D., Cuong, N. P., Thang, T. C., Huong, V. M., Chien, V. C., Phuong, N., Montomoli, E., Holt, R., Scorza, F. B., Flores, J., & Tewari, T. (2020). A Phase 2/3 double blinded, randomized, placebo-controlled study in healthy adult participants in Vietnam to examine the safety and immunogenicity of an inactivated whole virion, alum adjuvanted, A(H5N1) influenza vaccine (IVACFLU-A/H5N1). *Vaccine*, *38*(6), 1541–1550. https://doi.org/10.1016/j.vaccine.2019.11.059