Approval Date: September 9, 2016

Product: None

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

Manufacturer: ID Biomedical Corporation of Quebec

Indication: For active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted is approved for use in persons (6 months and older) at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.

Description: Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, for intramuscular injection, is a non-infectious, 2-component monovalent, AS03-adjuvanted vaccine.

BLA: 125419

Regulatory Milestone: e. In November 2013, Q-Pan H5N1 was licensed for use in adults 18 years of age and older for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. On September 8, 2014, a meeting was held between CBER and GSK to address GSK's overall pediatric study plan that was part of the post-marketing pediatric requirements for the Q-Pan H5N1 BLA

PDUFA Goal Date: September 9, 2016

Package Insert: Package Insert -Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

Summary Basis for Regulatory Approval: September 9, 2016 Summary Basis of Regulatory Action - Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted

European Public Assessment Report: No data

Advisory Committee:

The supplements did not require input from the Vaccines and Related Biological Products Advisory Committee.

NCT Numbers:

- NCT01788228
- NCT01416571
- NCT00742885
- NCT01910519
- NCT00616928
- NCT00695669
- NCT00719043
- NCT02719743
- NCT03701061
- NCT01310413
- NCT02213354
- NCT03318315

EudraCT Numbers:

- 2015-003458-42
- 2016-001898-32
- 2015-001979-46
- 2006-004041-42
- 2008-003871-32
- 2006-001168-22
- 2012-001683-29
- 2006-001281-16
- 2006-005477-22
- 2011-003512-23
- 2007-000115-28

Publications:

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universal vaccine against H5N1 lineages. *Journal of virology*, *84*(22), 11822–11830. https://doi.org/10.1128/JVI.00891-10

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