Approval Date: July 9, 2020

Product: FluMist

Proper Name: Influenza Vaccine

Manufacturer: Medimmune, LLC

Indication: For active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.

Description:

BLA: 125020

Regulatory Milestone:

FluMist was approved for use in healthy subjects 5-49 years of age in June 2003. A formulation change was approved in January 2006. The original frozen formulation required frozen storage until use. Studies submitted in the current label supplement BLA used either frozen or liquid FluMist. Extension of the indication to individuals 2 – < 60 months was approved on September 17, 2007.

PDUFA Goal Date: None

Package Insert: Not available

Summary Basis for Regulatory Approval: May 26, 2011 Summary Basis for Regulatory Action - FluMist

European Public Assessment Report: None

Advisory Committee:

The Vaccines and Related Biologics Advisory Committee (VRBPAC) was not convened to discuss this supplement. Advice from VRBPAC was not thought to be critical to the review because the data and proposed changes to labeling do not affect the indication or use of the vaccine or reveal major safety concerns.

Safety:

The clinical review of safety data from the studies submitted to this sBLA did not identify any new safety concerns that warrant revisions in labeling.

NCT Numbers:

- NCT01938170
- NCT03701061
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- NCT01173601

EudraCT Numbers:

- 2017-000849-50
- 2018-003701-26
- 2017-000848-17
- 2013-000492-32
- 2014-004634-26
- 2007-007859-14
- 2008-007510-30
- 2009-013223-37
- 2006-005036-24
- 2007-002066-35
- 2006-003577-27

Publications:

- Cha, T. A., Kao, K., Zhao, J., Fast, P. E., Mendelman, P. M., & Arvin, A. (2000). Genotypic stability of cold-adapted influenza virus vaccine in an efficacy clinical trial. *Journal of clinical microbiology*, *38*(2), 839–845. https://doi.org/10.1128/JCM.38.2.839-845.2000
- Buonagurio, D. A., O'Neill, R. E., Shutyak, L., D'Arco, G. A., Bechert, T. M., Kazachkov, Y., Wang, H. P., DeStefano, J., Coelingh, K. L., August, M., Parks, C. L., Zamb, T. J., Sidhu, M. S., & Udem, S. A. (2006). Genetic and phenotypic stability of cold-adapted influenza viruses in a trivalent vaccine administered to children in a day care setting. *Virology*, *347*(2), 296–306. https://doi.org/10.1016/j.virol.2005.11.006

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- Bethell, D., Saunders, D., Jongkaewwattana, A., Kramyu, J., Thitithayanont, A., Wiboon-ut, S., Yongvanitchit, K., Limsalakpetch, A., Kum-Arb, U., Uthaimongkol, N., Garcia, J. M., Timmermans, A. E., Peiris, M., Thomas, S., Engering, A., Jarman, R. G., Mongkolsirichaikul, D., Mason, C., Khemnu, N., Tyner, S. D., … Pichyangkul, S. (2013). Evaluation of in vitro cross-reactivity to avian H5N1 and pandemic H1N1 2009 influenza following prime boost regimens of seasonal influenza vaccination in healthy human subjects: a randomised trial. *PloS one*, *8*(3), e59674. https://doi.org/10.1371/journal.pone.0059674