Approval Date: September 15, 2020

Product: Varivax®

Proper Name: Varicella Virus Vaccine Live

Manufacturer: Merck Shark & Dohme Corp.

Indication: Active immunization for the prevention of varicella in individuals 12 months of age and older.

Description: VARIVAX is a preparation of the Oka/Merck strain of live, attenuated varicella virus. The virus was initially obtained from a child with wild-type varicella, then introduced into human embryonic lung cell cultures, adapted to and propagated in embryonic guinea pig cell cultures and finally propagated in human diploid cell cultures (WI-38).

BLA: BL 103552

Regulatory Milestone: No Data available

PDUFA Goal Date: February 20, 2017

Package Insert:

- Package Insert - Varivax (Frozen)
- Package Insert - Varivax (Refrigerator)

Summary Basis for Regulatory Approval: February 16, 2017 Summary Basis for Regulatory Action - VARIVAX

European Public Assessment Report: No Data available

Advisory Committee:

A Vaccines and Related Biologics Products Advisory Committee (VRBPAC) meeting was not held for this supplement, as there were no issues or concerns that presented during the course of review of the supplement that required consult from the advisory committee.

Safety:

All subjects were followed for safety (daily temperatures, injection-site adverse events, and systemic adverse events) for 42 days after each vaccination. All subjects were followed for serious adverse events from the time of enrollment until the end of the study. In addition, medically-attended events were collected through 180 days after completing the 42-day safety follow-up post Dose 2. Although no formal hypothesis was tested regarding safety, a summary of safety results following each dose of vaccine demonstrated that the safety profile of the two vaccines was similar. Overall, the two vaccination groups were comparable in terms of the incidence rates of adverse events overall, systemic adverse events, injection-site adverse events, vaccine-related adverse events, and serious adverse events.

NCT Numbers:

- NCT02026089
- NCT01331161
- NCT00156559
- NCT01581164
- NCT02624375
- NCT01911065
- NCT00406081
- NCT03771157
- NCT03239873
- NCT00871117
- NCT01137669
- NCT04169009
- NCT00000837
- NCT03702231
- NCT00921999
- NCT00197015
- NCT01474720
- NCT02114333
- NCT00861744
- NCT01049035
- NCT01346293
- NCT00001125
- NCT00289783
- NCT00505063
- NCT00851786
- NCT02184572
- NCT01681992
- NCT00345683

- NCT03893448
- NCT03621670
- NCT01544764
- NCT04398706
- NCT02538341
- NCT03620162
- NCT03993717
- NCT01702428
- NCT00483574
- NCT01577979
- NCT03537508
- NCT00806195
- NCT03673462
- NCT03691610
- NCT03563183
- NCT00474526
- NCT00578175
- NCT00422292

EudraCT Numbers:

- 2004-002586-21
- 2019-003903-36
- 2008-007235-40
- 2017-001444-35
- 2017-001910-27
- 2015-001509-15
- 2011-002946-11
- 2011-005860-31
- 2011-004891-12
- 2011-004905-26
- 2005-002352-18
- 2011-000758-41
- 2011-006161-18
- 2016-004904-74
- 2004-002669-19
- 2016-003268-37
- 2005-006066-34
- 2011-004638-32

Publications:

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