Approval Date: September 16, 2016

Product: DAPTACEL

Proper Name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

Manufacturer: Sanofi Pasteur, Ltd.

Indication: Indicated for active immunization against diphtheria, tetanus and pertussis as a five-dose series in infants and children 6 weeks through 6 years of age (prior to 7th birthday).

Description: DAPTACEL is a sterile isotonic suspension of pertussis antigens and diphtheria and tetanus toxoids adsorbed on aluminum phosphate, for intramuscular injection.

BLA: 103666

Regulatory Milestone: No data available

PDUFA Goal Date: September 16, 2016

Package Insert: Package Insert - DAPTACEL

Summary Basis for Regulatory Approval: September 16, 2016 Summary Basis of Regulatory Action - DAPTACEL

European Public Assessment Report: No data available

Advisory Committee:

Did not require input from Vaccines and Related Biological Products Advisory Committee.

Safety:

There were no primary endpoints for safety; however, safety was evaluated as secondary (descriptive) endpoints and included 7 days post-vaccination assessment of solicited local and systemic reactions, 30 days post-vaccination assessment of unsolicited AEs, and monitoring of serious adverse events throughout the study duration. The most frequently reported solicited local reaction at either the Menactra or DAPTACEL injection site across all groups was pain, reported in 52% to 72% of subjects at the DAPTACEL site and 52% to 61% of subjects at the Menactra site. The most frequently reported solicited systemic reaction across all groups was myalgia across all study groups, reported in 25.8% to 46.2% of subjects following administration of DAPTACEL alone or with a concomitant vaccine, and in 24.2% to 37.3% subjects following administration of Menactra alone or with a concomitant vaccine. The reported rates and types of unsolicited AEs are similar to that seen in the general population for children 4 to 6 years of age. None of the three reported SAEs were considered related to study vaccination and there were no deaths reported during the study

NCT Numbers:

- NCT00662870
- NCT00258895
- NCT00802867
- NCT01346293
- NCT00467519
- NCT00355121
- NCT02118961
- NCT01346293
- NCT00289913
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- NCT01444781
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- NCT01659996
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- NCT02643472
- NCT00385255
- NCT02589678
- NCT02199691
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- NCT04490018

EudraCT Numbers:

- 2015-003500-23
- 2011-004095-10

Publications:

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