Approval Date: May 24, 2019

Product: ActHIB

Proper Name: Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)

Manufacturer: Sanofi Pasteur, SA

Indication: ActHIB vaccine is indicated for the active immunization of infants and children 2 months through 5 years of age for the prevention of invasive disease caused by H influenzae type b.

Description: ActHIB vaccine is a sterile, lyophilized powder to be reconstituted with saline diluent (0.4% Sodium Chloride) for intramuscular administration only. The vaccine consists of the Haemophilus influenzae type b capsular polysaccharide (polyribosyl-ribitol-phosphate, PRP), a high-molecular weight polymer prepared from the H. influenzae type b strain 1482 grown in a semi-synthetic medium, covalently bound to tetanus toxoid.

BLA: 103935

Regulatory Milestone: No data

PDUFA Goal Date: No data

Package Insert: Package Insert - ActHIB

Summary Basis for Regulatory Approval:

- Summary for Basis of Approval (ActHIB combined with Tripedia) - Tripedia
- Summary Basis for Regulatory Action - ActHIB

European Public Assessment Report: No data

Advisory Committee:

Data regarding the safety and immunogenicity of ActHlB ™ when reconstituted with CLI DTP were presented and discussed at the October 28, 1992 Vaccines and Related Biological Products Advisory Committee meeting. Data on use of Tripedia™ to reconstitute ActHIB™ were not formally presented to the Advisory Committee.

NCT Numbers:

- NCT01000974
- NCT00359983
- NCT01732198
- NCT01214889
- NCT01578070
- NCT01062477
- NCT01379846
- NCT02139228
- NCT03891758
- NCT00197236
- NCT02817451
- NCT01105559
- NCT00255047
- NCT01177722
- NCT03207750
- NCT00228917
- NCT00134719
- NCT00317187
- NCT00317135
- NCT00680914
- NCT01251133
- NCT01019772
- NCT01061541
- NCT01977170
- NCT01025544
- NCT00342628
- NCT00345579
- NCT00911144
- NCT00729001
- NCT00317122
- NCT00290303
- NCT00348881
- NCT02428491
- NCT02697474
- NCT00326118
- NCT02140047
- NCT00127855
- NCT02806284
- NCT02560272
- NCT00291343
- NCT01948193
- NCT00197275
- NCT00614614
- NCT00772928
- NCT00534833
- NCT00129129
- NCT00696423
- NCT02992925
- NCT00343889
- NCT00473668
- NCT02096263
- NCT00412854
- NCT00453570
- NCT00345683
- NCT00317161
- NCT00401531
- NCT01777308
- NCT00334607
- NCT00514709
- NCT00771849
- NCT00454987
- NCT01457508
- NCT00662870
- NCT02610348
- NCT00654901
- NCT01444781
- NCT01226953
- NCT01839175
- NCT00802867
- NCT00316680
- NCT00814710
- NCT00879827
- NCT00547248
- NCT00289783
- NCT01337167
- NCT00303316
- NCT00169442
- NCT00373958
- NCT00332566
- NCT00655148
- NCT03893448
- NCT01309646
- NCT02094833
- NCT01977196
- NCT03621670
- NCT01457495
- NCT00317109
- NCT00291967
- NCT00436007
- NCT00136604
- NCT00855855
- NCT01983540
- NCT00344318
- NCT00341250
- NCT03620162
- NCT00323622
- NCT00315055
- NCT00313911
- NCT00362336
- NCT04071379

- NCT01340898
- NCT02095314
- NCT00474526
- NCT00551629
- NCT01098474
- NCT03673462
- NCT00551915
- NCT01986322
- NCT02643472
- NCT00657709
- NCT00667602

EudraCT Numbers:

- 2015-001530-25
- 2012-004060-22
- 2013-004304-19
- 2013-004194-27
- 2015-005293-38
- 2012-002401-22
- 2005-002352-18
- 2005-006066-34
- 2011-004095-10
- 2017-000665-79
- 2016-003526-16

Publications:

- Scheifele, D. W., Meekison, W., Guasparini, R., Roberts, A., Barreto, L., Thipphawong, J., & Wiltsey, S. (1995). Evaluation of booster doses of Haemophilus influenzae type b-tetanus toxoid conjugate vaccine in 18-month-old children. *Vaccine*, *13*(1), 104–108. https://doi.org/10.1016/0264-410x(95)80019-a
- Vidor, E., Hoffenbach, A., & Fletcher, M. A. (2001). Haemophilus influenzae type b vaccine: reconstitution of lyophilised PRP-T vaccine with a pertussis-containing paediatric combination vaccine, or a change in the primary series immunisation schedule, may modify the serum anti-PRP antibody responses. *Current medical research and opinion*, *17*(3), 197–209. https://doi.org/10.1185/0300799039117063
- Cherian, T., Thomas, N., Raghupathy, P., Durot, I., & Dutta, A. (2002). Safety and immunogenicity of Haemophilus influenzae type B vaccine given in combination with DTwP at 6, 10 and 14 weeks of age. *Indian pediatrics*, *39*(5), 427–436.
- Gibb, D., Spoülou, V., Giacomelli, A., Griffiths, H., Masters, J., Misbah, S., Nokes, L., Pagliaro, A., Giaquinto, C., & Kroll, S. (1995). Antibody responses to Haemophilus influenzae type b and Streptococcus pneumoniae vaccines in children with human immunodeficiency virus infection. *The Pediatric infectious disease journal*, *14*(2), 129–135. https://doi.org/10.1097/00006454-199502000-00009
- Carlsson, R. M., Claesson, B. A., Selstam, U., Fagerlund, E., Granström, M., Blondeau, C., & Hoffenbach, A. (1998). Safety and immunogenicity of a combined diphtheria-tetanus-acellular pertussis-inactivated polio vaccine-Haemophilus influenzae type b vaccine

administered at 2-4-6-13 or 3-5-12 months of age. *The Pediatric infectious disease journal*, *17*(11), 1026–1033. https://doi.org/10.1097/00006454-199811000-00013

- Centers for Disease Control and Prevention (CDC) (1996). FDA approval of a Haemophilus b Conjugate Vaccine combined by reconstitution with an acellular pertussis vaccine. *MMWR. Morbidity and mortality weekly report*, *45*(45), 993–995.