Approval Date: April 25, 2016

Product: Cervarix

Proper Name: Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant

Manufacturer: GlaxoSmithKline Biologicals

Indication: Prevention of cervical cancer, cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma in situ, and cervical intraepithelial neoplasia (CIN) grade 1, caused by oncogenic human papillomavirus (HPV) types 16 and 18, in females9 through 25 years of age.

Description: CERVARIX [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant] is a non-infectious recombinant, AS04-adjuvanted vaccine that contains recombinant L1 protein, the major antigenic protein of the capsid, of oncogenic HPV types 16 and 18.

BLA: BL 125259

Regulatory Milestone:

Cervarix was licensed in the United Stated on October 16, 2009, under BLA STN 125259/0. In the October 2009 Cervarix BLA approval letter, Postmarketing Commitment (PMC) #5a requested submission of the end-of-study analysis report (Month 48) for Study HPV-008. GSK satisfied this PMC with submission of the report on December 22, 2010 (STN 125259/182).

PDUFA Goal Date: July 26, 2014

Package Insert: Package Insert - Cervarix

Summary Basis for Regulatory Approval: July 17, 2014 Summary Basis for Regulatory Action - CERVARIX

European Public Assessment Report: Human medicine European public assessment report (EPAR): Cervarix

Advisory Committee:

A Vaccines and Related Biological Products Advisory Committee meeting for discussion of the data in this submission was not held because review of this supplement did not raise concerns which would have benefited from an advisory committee discussion.

NCT Numbers:

- NCT02979535
- NCT02567955
- NCT01456715
- NCT00730847
- NCT01914367
- NCT00534638
- NCT01905462
- NCT01187927
- NCT01498627
- NCT01551537
- NCT03671369
- NCT01755689
- NCT00316693
- NCT00956553
- NCT00586339
- NCT03728881
- NCT01953822
- NCT01290393
- NCT01101542
- NCT02082639
- NCT01031069
- NCT01153906
- NCT04590521
- NCT01381575
- NCT00485732
- NCT02276521
- NCT00549900
- NCT03747770
- NCT02296255
- NCT00196937
- NCT01627561
- NCT00552279
- NCT00546078
- NCT00426361
- NCT00492544
- NCT01190189
- NCT00423046
- NCT00799825
- NCT00689741
- NCT00337818
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- NCT02811068
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- NCT00578227
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- NCT00250276
- NCT03180034
- NCT00294047
- NCT00122681
- NCT00481767
- NCT00456807
- NCT00309166
- NCT00541970
- NCT04301154
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- NCT00518336
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- NCT01717118
- NCT01277042
- NCT03675256
- NCT00947115
- NCT03355820
- NCT01393470
- NCT01190176
- NCT02837926
- NCT01168401
- NCT03296397
- NCT04391647
- NCT00937950
- NCT00369824
- NCT01824537
- NCT00359619
- NCT01702337
- NCT03265743
- NCT02234921

EudraCT Numbers: None

Publications:

- Van Damme, P., Leroux-Roels, G., Simon, P., Foidart, J. M., Donders, G., Hoppenbrouwers, K., Levin, M., Tibaldi, F., Poncelet, S., Moris, P., Dessy, F., Giannini, S. L., Descamps, D., & Dubin, G. (2014). Effects of varying antigens and adjuvant systems on the immunogenicity and safety of investigational tetravalent human oncogenic papillomavirus vaccines: results from two randomized trials. *Vaccine*, *32*(29), 3694–3705. https://doi.org/10.1016/j.vaccine.2014.03.040
- Gilca, V., Sauvageau, C., Boulianne, N., De Serres, G., Crajden, M., Ouakki, M., Trevisan, A., & Dionne, M. (2015). The effect of a booster dose of quadrivalent or bivalent HPV vaccine when administered to girls previously vaccinated with two doses of quadrivalent HPV vaccine. *Human vaccines & immunotherapeutics*, *11*(3), 732–738. https://doi.org/10.1080/21645515.2015.1011570
- Haskins-Coulter, T., Southern, J., Andrews, N., & Miller, E. (2017). Reactogenicity of Cervarix and Gardasil human papillomavirus (HPV) vaccines in a randomized single blind trial in healthy UK adolescent females. *Human vaccines & immunotherapeutics*, *13*(6), 1–9. https://doi.org/10.1080/21645515.2016.1277846
- Godi, A., Panwar, K., Haque, M., Cocuzza, C. E., Andrews, N., Southern, J., Turner, P., Miller, E., & Beddows, S. (2019). Durability of the neutralizing antibody response to vaccine and non-vaccine HPV types 7 years following immunization with either Cervarix® or Gardasil® vaccine. *Vaccine*, *37*(18), 2455–2462. https://doi.org/10.1016/j.vaccine.2019.03.052