

Approval Date: [December 16, 2010](#)

Product: TICE BCG

Proper Name: BCG Live

Manufacturer: Organon Teknika Corp., LLC

Indication: For the treatment and prophylaxis of carcinoma *in situ* (CIS) of the urinary bladder. For the prophylaxis of primary or recurrent state Ta and/or T1 papillary tumors following transurethral resection (TUR).

Description: TICE® BCG for intravesical use, is an attenuated, live culture preparation of the Bacillus of Calmette and Guerin (BCG) strain of Mycobacterium bovis.

BLA: 102821

Regulatory Milestone: No data available

PDUFA Goal Date: No data available

Package Insert: [Package Insert – TICE BCG](#)

Summary Basis for Regulatory Approval: [Summary for Basis of Approval – BCG Vaccine](#)

European Public Assessment Report: None

Advisory Committee:

On December 16, 1996, the Oncologic Drugs Advisory Committee reviewed the data supporting the use of TICE BCG for prophylaxis against recurrent papillary carcinoma of the

urinary bladder. The committee was asked to consider five questions, proposed by the FDA, on the efficacy, safety, and infectious disease complications of using TICE BCG to treat papillary tumors of the bladder. Although the committee felt that the Nijmegen study did not provide evidence of the activity of TICE BCG for this indication, the committee did agree that the SWOG study 8795 data did support the use of TICE BCG in the prevention of TaT₁ tumors. The committee also responded positively about the overall safety and effectiveness of TICE BCG in the prophylactic therapy of tumors of the bladder. With respect to infectious disease concerns, the committee recommended that a more extensive discussion of infectious disease management, and especially the use of prophylactic isoniazid to treat inflammatory responses, should be included in the label.

NCT Numbers:

- NCT04632537
- NCT02015104
- NCT03213405
- NCT02326168
- NCT01113281
- NCT02013245
- NCT04373291
- NCT04369794
- NCT04461379
- NCT04659941
- NCT03548233
- NCT02259608
- NCT02729571
- NCT02413502
- NCT04641858
- NCT04475302
- NCT04542330
- NCT01479972
- NCT00749034
- NCT04417335
- NCT03152903
- NCT04327206
- NCT03888924
- NCT02692963
- NCT01650389
- NCT02010203
- NCT01119521
- NCT04658680
- NCT04630730
- NCT02430506
- NCT03400878
- NCT02075203
- NCT00331474
- NCT01378312
- NCT04445428
- NCT02391415
- NCT00568854
- NCT02114255
- NCT04648800
- NCT04383925

EudraCT Numbers:

- 2017-003581-27
- 2018-001967-22
- 2005-001775-35
- 2011-000607-41
- 2010-019181-91
- 2017-002979-26
- 2018-000150-22

Publications:

- Rentsch, C. A., Birkhäuser, F. D., Biot, C., Gsponer, J. R., Bisiaux, A., Wetterauer, C., Lagranderie, M., Marchal, G., Orgeur, M., Bouchier, C., Bachmann, A., Ingersoll, M. A., Brosch, R., Albert, M. L., & Thalmann, G. N. (2014). Bacillus Calmette-Guérin strain differences have an impact on clinical outcome in bladder cancer immunotherapy. *European urology*, 66(4), 677–688. <https://doi.org/10.1016/j.eururo.2014.02.061>
- Svatek, R. S., Tangen, C., Delacroix, S., Lowrance, W., & Lerner, S. P. (2018). Background and Update for S1602 "A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-naïve High-grade Non-muscle-invasive Bladder Cancer. *European urology focus*, 4(4), 522–524. <https://doi.org/10.1016/j.euf.2018.08.015>
- Steinberg RL, Brooks NA, Thomas LJ, Mott SL, O'Donnell MA. Bacillus Calmette-Guerin strain may not effect recurrence-free survival when used intravesically with interferon-alpha2b for non-muscle-invasive bladder cancer. *Urol Oncol*. 2017 May;35(5):201-207. doi: 10.1016/j.urolonc.2016.11.016. Epub 2016 Dec 29. PMID: 28041998
- Hoft, D. F., Blazevic, A., Selimovic, A., Turan, A., Tennant, J., Abate, G., Fulkerson, J., Zak, D. E., Walker, R., McClain, B., Sadoff, J., Scott, J., Shepherd, B., Ishmukhamedov, J., Hokey, D. A., Dheenadhayalan, V., Shankar, S., Amon, L., Navarro, G., Podyminogin, R., ... Steinberg, S. (2016). Safety and Immunogenicity of the Recombinant BCG Vaccine AERAS-422 in Healthy BCG-naïve Adults: A Randomized, Active-controlled, First-in-human Phase 1 Trial. *EBioMedicine*, 7, 278–286. <https://doi.org/10.1016/j.ebiom.2016.04.010>
- Vegt, P. D., Witjes, J. A., Witjes, W. P., Doesburg, W. H., Debruyne, F. M., & van der Meijden, A. P. (1995). A randomized study of intravesical mitomycin C, bacillus Calmette-Guerin Tice and bacillus Calmette-Guerin RIVM treatment in pTa-pT1 papillary carcinoma and carcinoma in situ of the bladder. *The Journal of urology*, 153(3 Pt 2), 929–933.
- Peters, K. M., Diokno, A. C., Steinert, B. W., & Gonzalez, J. A. (1998). The efficacy of intravesical bacillus Calmette-Guerin in the treatment of interstitial cystitis: long-term followup. *The Journal of urology*, 159(5), 1483–1487. <https://doi.org/10.1097/00005392-199805000-00019>

- Lamm, D. L., DeHaven, J. I., Shriver, J., & Sarosdy, M. F. (1991). Prospective randomized comparison of intravesical with percutaneous bacillus Calmette-Guerin versus intravesical bacillus Calmette-Guerin in superficial bladder cancer. *The Journal of urology*, 145(4), 738–740. [https://doi.org/10.1016/s0022-5347\(17\)38439-2](https://doi.org/10.1016/s0022-5347(17)38439-2)
- Hoft, D. F., Blazevic, A., Abate, G., Hanekom, W. A., Kaplan, G., Soler, J. H., Weichold, F., Geiter, L., Sadoff, J. C., & Horwitz, M. A. (2008). A new recombinant bacille Calmette-Guérin vaccine safely induces significantly enhanced tuberculosis-specific immunity in human volunteers. *The Journal of infectious diseases*, 198(10), 1491–1501. <https://doi.org/10.1086/592450>
- Sarosdy, M. F., Tangen, C. M., Weiss, G. R., Nestok, B. R., Benson, M. C., Schellhammer, P. F., Sagalowsky, A. I., Wood, D. P., Jr, & Crawford, E. D. (2005). A phase II clinical trial of oral bropridine in combination with intravesical bacillus Calmette-Guérin for carcinoma in situ of the bladder: a Southwest Oncology Group Study. *Urologic oncology*, 23(6), 386–389. <https://doi.org/10.1016/j.urolonc.2005.05.028>
- Karakousis, C. P., & Emrich, L. J. (1987). Adjuvant treatment of malignant melanoma with DTIC + estracyt or BCG. *Journal of surgical oncology*, 36(4), 235–238. <https://doi.org/10.1002/jso.2930360404>