Matching-adjusted Indirect Comparisons (MAIC) of TAR-200 vs. FDA-approved novel agents in BCG-unresponsive High-risk NMIBC with CIS[1]

Background[1,2]

An MAIC is a methodology that allows for statistical comparison of efficacy between two drugs in the absence of head-to-head comparative data by:

Matching the individual patient data from SunRISe-1 and summary-level data from the USPI and primary journal publications of the comparators

Assigning weights to the outcomes of patients in the trials, based on each patient's **proximity of baseline characteristics to the published trial aggregate baseline characteristics**

An unanchored MAIC is the only methodology available to conduct an ITC in the BCG unresponsive HR NMIBC CIS setting since there is no common comparator between trials

Baseline characteristics

MAIC assumes comparator studies have similar study design and patient characteristics after matching. Adjustment for prognostic factors and treatment effect modifiers is required.*

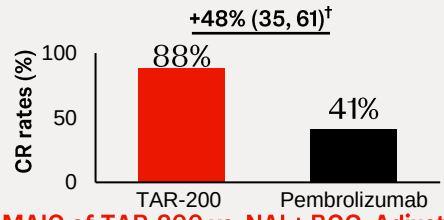
Variable	Categories	SunRISe-1[3] (N=85)	KEYNOTE-057[4,5] (N=96)	CS-003[6,7] (N=98)	QUILT 3.032[8,9] (N=77)
Age in years	Median (Range)	71 (40-88)	73 (44-92)	70 (44-89)	73 (50-91)
Gender	Male %	80.0	84	88	86
	Female %	20.0	16	12	14
Race	White %	87.1	67	92	90
	Non-white %	12.9	33	8	10
ECOG	0 %	91.8	73	90	83
	1+ , %	8.2	27	10	17
# Prior BCG instillation	Median	12	12	12	12
Stage	CIS+T1 %	10.6	13	5	10
	CIS+Ta %	22.4	25	19	21
	CIS alone %	67.1	63	76	69

Results

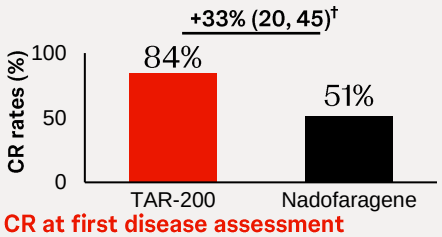
MAICs of TAR-200 vs. FDA-approved novel agents: adjusted CR at any time (absolute rate differences)

P<0.05 for all comparisons

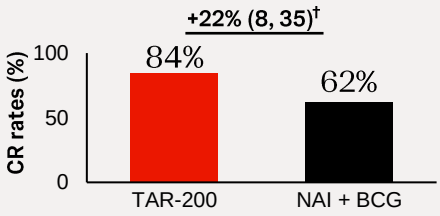
TAR-200 vs. Pembrolizumab



TAR-200 vs. Nadofaragene



TAR-200 vs. NAI + BCG



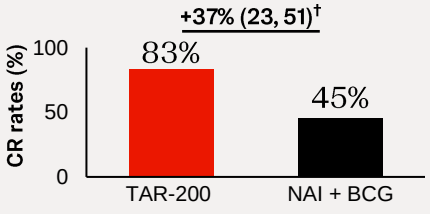
MAIC of TAR-200 vs. NAI + BCG: Adjusted CR at first disease assessment (absolute rate difference)

To account for CR rate after reinduction with NAI + BCG in QUILT 3.032

Anytime CR (62%) = **48** responders / **77** patients

24 patients received reinduction: **13** of which achieved CR.[9]

48 total responders – **13** responders after reintroduction / **77** total patients = **45.5% of patients achieved CR at first disease assessment**



TAR-200 demonstrated **significantly higher CR rate** at any time over FDA approved novel agents in BCG-unresponsive HR NMIBC with CIS, as well as at first disease assessment compared to NAI + BCG.

*The MAIC methodology can only adjust for observed and reported baseline characteristics. Any confounders not consistently reported or missing across studies may impact internal validity. Some differences in study design and outcomes can introduce biases that the MAIC cannot fully address. †Rate difference has been rounded.

BCG, Bacillus Calmette Guerin; CIS, carcinoma in situ; CR, complete response; ECOG, Eastern Cooperative Oncology Group; HR, high-risk; ITC, indirect treatment comparison; nadofaragene, nadofaragene firadenovec-vncg; NAI, nogapendekin alfa inbakicept-pmln; NMIBC, non-muscle invasive bladder cancer; USPI, US prescribing information.

1. Daneshmand et al. Presented at The Professional Society for Health Economics and Outcomes Research (ISPOR); May 16, 2025; Montreal, QC, Canada. 2. Signorovitch JE, et al. *Value Health.* 2012 Sep-Oct;15(6):940-7. 3. Jacob J. Presented at American Urology Association Annual Meeting; April 26, 2025; Las Vegas, NV, USA. 4. Keytruda. Prescribing information. Merck & Co., Inc; 2014. 5. Balar AV, et al. *Lancet Oncol.* Jul 2021;22(7):919-930. 6. Adstiladrin. Prescribing information. Ferring Pharmaceuticals; 2022. 7. Boorjian SA, et al. *Lancet Oncol.* Jan 2021;22(1):107-117. 8. Anktiva. Prescribing information. ImmunityBio Inc.; 2024. 9. Chamie K, et al. *NEJM Evidence.* 2023;2(1).

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