

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette-Guérin-Unresponsive High-Risk Non-Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

¹Department of Urology, Upstate Medical University, Syracuse, NY; ²University Hospital 12 de Octubre, Madrid, Spain; ³Department of Urology, Bichat-Claude Bernard Hospital, Assistance Publique-Hôpitaux de Paris, Université de Paris Cité, Paris, France; ⁴Department of Urology, IRCCS "Regina Elena" National Cancer Institute, Rome, Italy; ⁵Department of Urology, UT Southwestern Medical Center, Dallas, TX; ⁶Associated Medical Professionals of NY, Syracuse, NY; ⁷AZ Sint-Jan Hospital Brugge-Oostende, Bruges, Belgium; ⁸IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; ⁹Department of Surgical Oncology, Princess Margaret Cancer Center, University Health Network, Toronto, Canada; ¹⁰Department of Urology, Westmead Hospital, Westmead, New South Wales, Australia, and Discipline of Surgery, Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia; ¹¹Colorado Urology, Lakewood, CO; ¹²Department of Urology, Pusan National University Yangsan Hospital, Pusan National University School of Medicine, Yangsan, Korea; ¹³Department of Urology, Münster University Medical Center, Münster, Germany; ¹⁴Clinical Oncology, Janssen Research & Development, Raritan, NJ; ¹⁵Janssen Research & Development, High Wycombe, UK; ¹⁶Clinical Oncology, Janssen Research & Development, Lexington, MA; ¹⁷Janssen Research & Development, Spring House, PA; ¹⁸Department of Medical Oncology, Netherlands Cancer Institute, Amsterdam, Netherlands



Click anywhere to view this interactive poster

<https://www.congresshub.com/Oncology/GU2024/TAR-200/Jacob>

Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from ASCO® or the author of this poster.



Presented by JM Jacob at the 2024 ASCO Genitourinary Cancers Symposium; January 25-27, 2024; San Francisco, CA, USA

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

KEY TAKEAWAYS

- Many patients with HR NMIBC CIS unresponsive to BCG refuse RC, highlighting the need for bladder-sparing therapy
- In this analysis, no responders to TAR-200 underwent RC, indicating the potential benefit of bladder-sparing treatment options for patients with HR NMIBC
- TAR-200 was associated with a CR rate of 77% in patients with HR NMIBC CIS recurrent after BCG in a preliminary analysis of SR-1 and led to Food and Drug Administration Breakthrough Therapy Designation

BCG, bacillus Calmette–Guérin; CIS, carcinoma in situ; CR, complete response; HR, high risk; NMIBC, non–muscle-invasive bladder cancer; RC, radical cystectomy; SR-1, SunRISe-1.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1 Study design

RESULTS

TABLE 1 Patient characteristics

FIGURE 2 Reasons for refusal of and ineligibility for RC

FIGURE 3 Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4 CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non-Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (Jacobj@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

CONCLUSIONS

- ✓ Efficacy and safety data from SR-1 support the ongoing investigation of TAR-200 in patients with BCG-unresponsive HR NMIBC⁶
- ✓ Over 90% of the patients with HR NMIBC CIS recurrent after BCG enrolled in Cohort 2 of SR-1 refused RC
- ✓ The most common reasons for refusal of RC were bladder preservation and QoL concerns
- ✓ A small number of patients in SR-1 were ineligible for RC; medical/surgical comorbidities and age were the primary reasons for ineligibility

BCG, bacillus Calmette–Guérin; CIS, carcinoma in situ; HR, high risk; NMIBC, non-muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; SR-1, SunRISe-1.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1 Study design

RESULTS

TABLE 1 Patient characteristics

FIGURE 2 Reasons for refusal of and ineligibility for RC

FIGURE 3 Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4 CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (Jacobj@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

INTRODUCTION

- Radical cystectomy (RC) is the standard of care for patients with bacillus Calmette–Guérin (BCG)-unresponsive high-risk non–muscle-invasive bladder cancer (HR NMIBC)^{1,2}
 - RC is often associated with significant morbidity and mortality and negatively impacts quality of life (QoL); many patients refuse or are ineligible for RC²
- In a systematic review of 160 real-world studies, less than 20% of patients with HR NMIBC recurrent after BCG underwent RC³
- TAR-200, a novel intravesical drug delivery system providing sustained release of gemcitabine within the bladder, is currently under investigation in patients with BCG-unresponsive HR NMIBC who are ineligible for or refuse RC in the ongoing phase 2b SunRISe-1 (SR-1) study (NCT04640623)⁴⁻⁶
 - SR-1 evaluated the safety and efficacy of TAR-200 + cetrelimab (Cohort 1), TAR-200 alone (Cohort 2), and cetrelimab alone (Cohort 3); as of protocol amendment 4, patients with papillary disease only (Cohort 4) will be enrolled and treated with TAR-200 alone (Figure 1)⁶
 - Results demonstrated a complete response (CR) rate of 76.7% and durable responses in patients with BCG-unresponsive HR NMIBC treated with TAR-200⁶
- This presentation reports reasons for refusal of or ineligibility for RC in patients enrolled in Cohort 2 of SR-1

NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1 Study design

RESULTS

TABLE 1 Patient characteristics

FIGURE 2 Reasons for refusal of and ineligibility for RC

FIGURE 3 Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4 CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

APPENDIX



Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

METHODS

- Refusal of and/or ineligibility for RC was documented in the electronic case report form

RC, radical cystectomy.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility for RC

FIGURE 3
Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

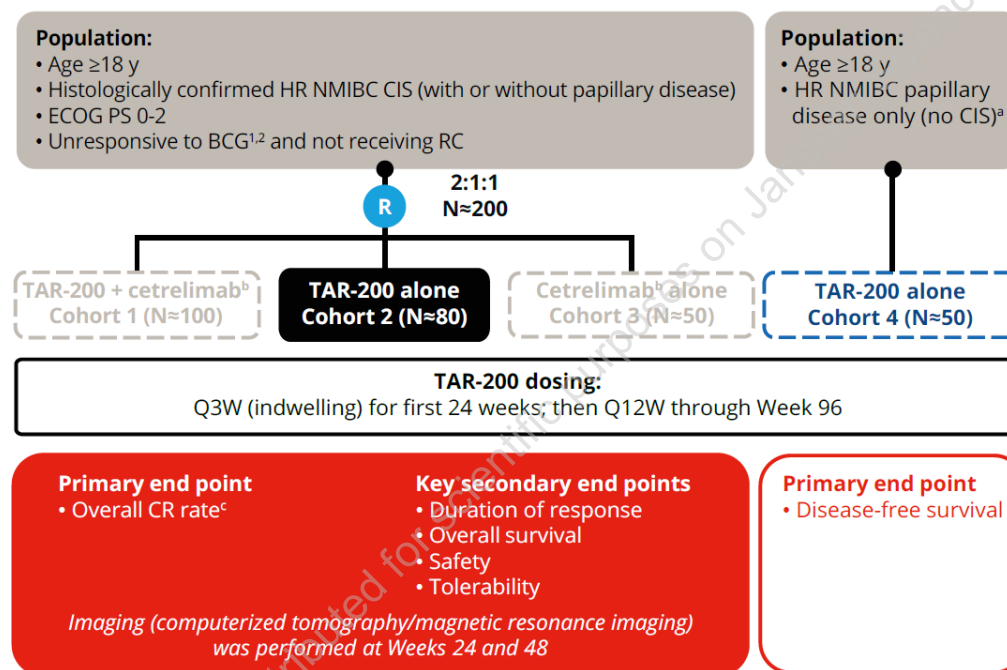
APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

METHODS

FIGURE 1: Study design



The clinical data cutoff was August 24, 2023.

^aPatients with BCG-unresponsive papillary-only HR NMIBC (high-grade Ta, any T1) per protocol amendment 4. ^bCetrelimab is an anti-PD-17; cetrelimab dosing was through Week 78. ^cA CR is defined as having a negative cystoscopy and negative (including atypical) centrally read urine cytology or positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative (including atypical) centrally read cytology at any time point. CIS, carcinoma in situ; ECOG PS, Eastern Cooperative Oncology Group performance status; PD-1, programmed cell death protein 1; Q3W, every 3 weeks; Q12W, every 12 weeks; R, randomization; y, year.

NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility for RC

FIGURE 3
Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

APPENDIX



Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non-Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

RESULTS (1/5)

- As of August 24, 2023, 54 patients were treated with TAR-200 alone (Table 1)
- The median (range) time from the most recent BCG dose to diagnosis of BCG-unresponsive disease was 3 (0-22) months
- Overall, 94.4% of patients refused RC; few (5.6%) were ineligible (Figure 2)
- Across age, sex, and nicotine use, most patients refused RC to preserve the bladder (Figure 3)
- No responders underwent RC as of data cutoff (n=23 of 23)
- Of 7 nonresponders, 1 patient who was a nonresponder at Week 12 went on to receive RC
- TAR-200 monotherapy was associated with an overall CR rate of 76.7% per central assessment and 80.0% per investigator assessment⁶ (Figure 4)
- TAR-200 monotherapy was generally well tolerated; most AEs were grade 1 or 2 and there were no deaths⁶

AE, adverse event; BCG, bacillus Calmette–Guérin; CR, complete response; RC, radical cystectomy.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility
for RC

FIGURE 3
Reasons for refusal of cystectomy by
age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC
CIS (Cohort 2)⁶

APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (Jacobj@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

RESULTS (2/5)

TABLE 1: Patient characteristics

	Cohort 2 N=54
Median (range) age, years	71 (40-85)
Male, n (%)	42 (77.8)
Race, n (%)	
White	37 (68.5)
Asian	4 (7.4)
Black or African American	2 (3.7)
Not reported	11 (20.4)
Baseline ECOG PS, n (%)	
0	52 (96.3)
1	2 (3.7)
Tumor stage, ^a n (%)	
CIS	36 (66.7)
CIS + pTa	14 (25.9)
CIS + pT1	4 (7.4)
Median (range) prior BCG doses	12 (7-42)
Medical conditions grade ≥ 2 , n (%)	36 (66.7)
Metabolic	27 (50.0)
Vascular	26 (48.1)
Cardiac	10 (18.5)
Nicotine users, n (%)	
Current	5 (9.3)
Former	30 (55.6)
Never	19 (35.2)

^aStages are mutually exclusive. BCG, bacillus Calmette–Guérin; CIS, carcinoma in situ; ECOG PS, Eastern Cooperative Oncology Group performance status.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility
for RC

FIGURE 3
Reasons for refusal of cystectomy by
age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC
CIS (Cohort 2)⁶

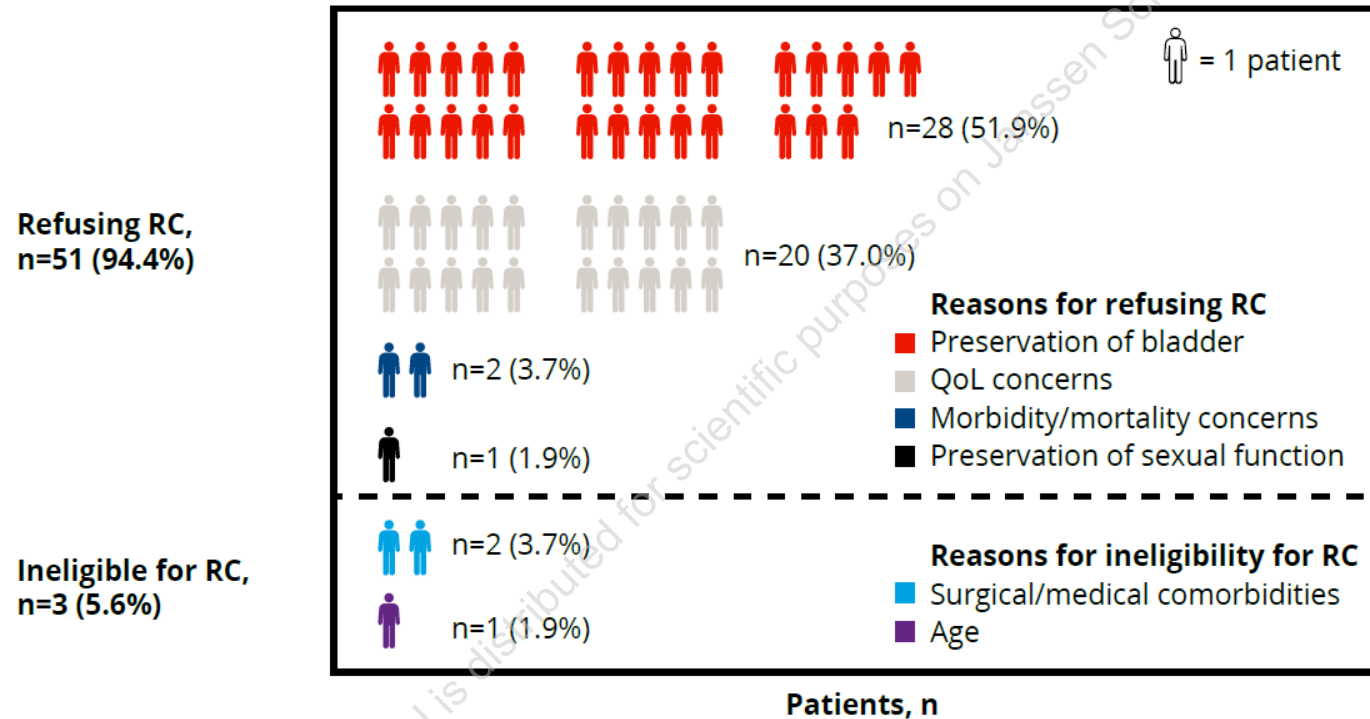
APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

RESULTS (3/5)

FIGURE 2: Reasons for refusal of and ineligibility for RC



QoL, quality of life; RC, radical cystectomy.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility for RC

FIGURE 3
Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

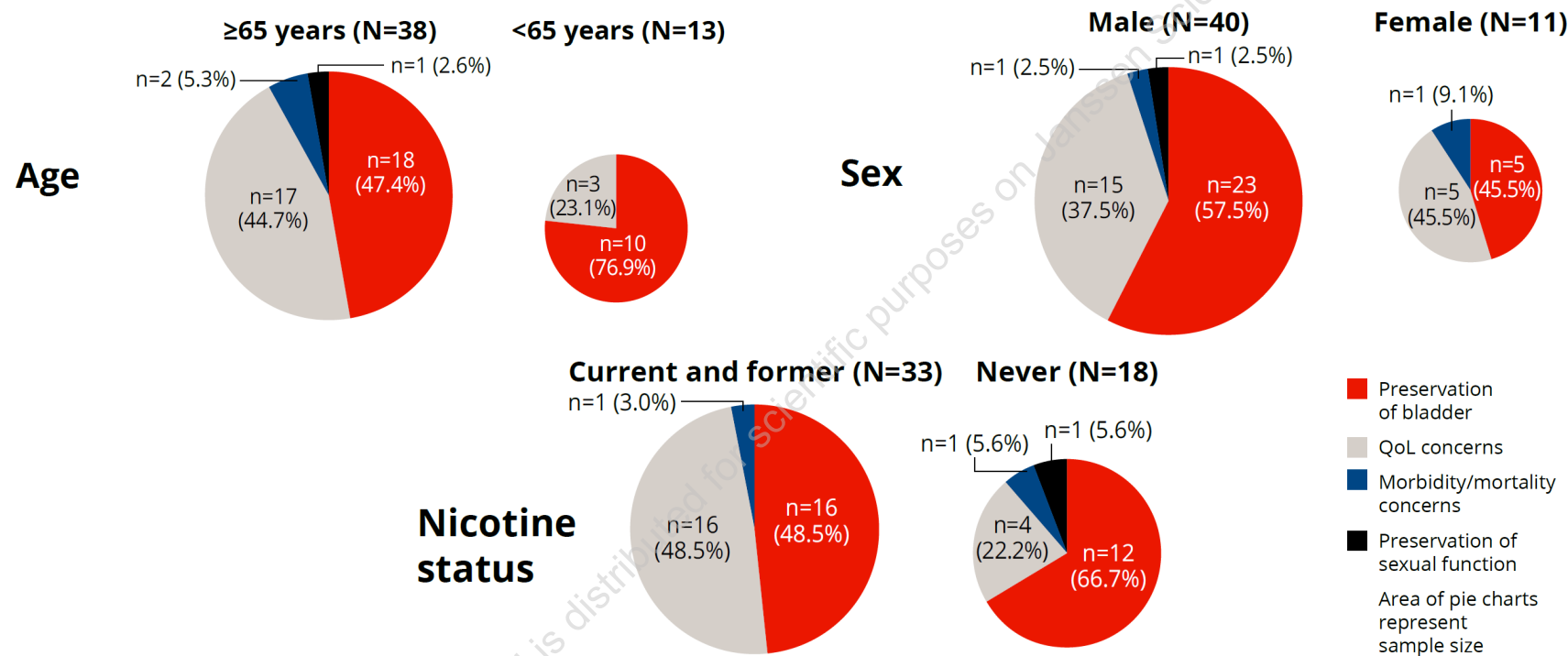
APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non-Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (Jacobj@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

RESULTS (4/5)

FIGURE 3: Reasons for refusal of cystectomy by age, sex, and nicotine status



QoL, quality of life.



NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility for RC

FIGURE 3
Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

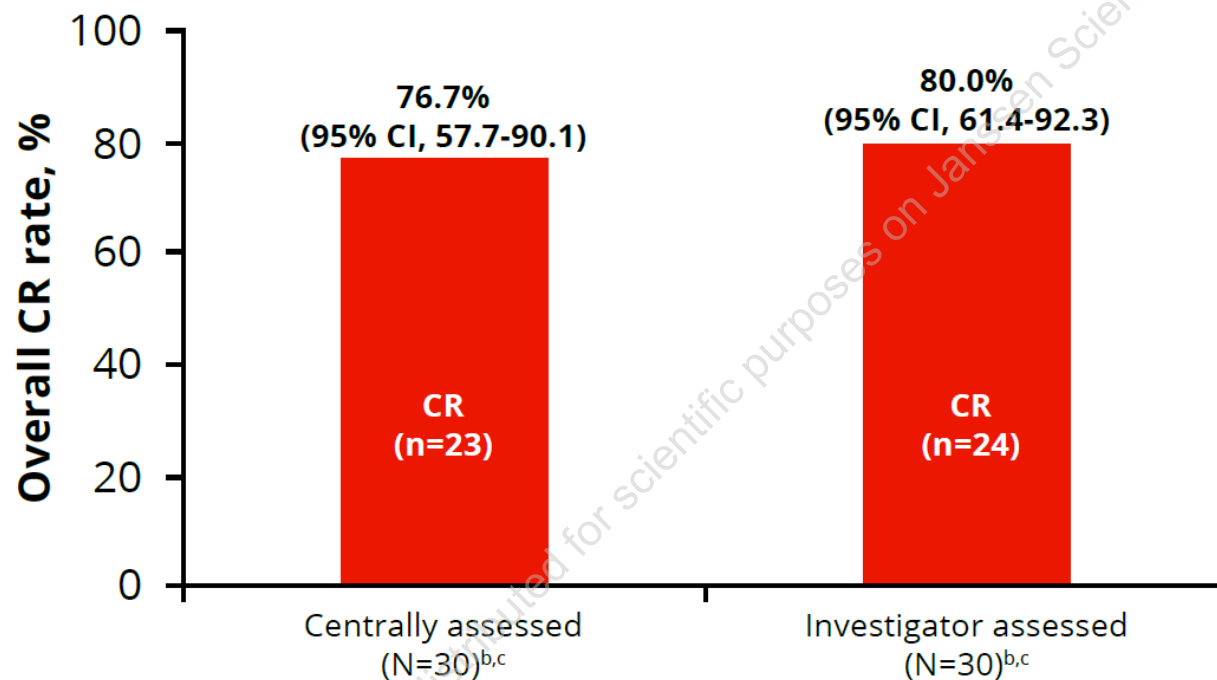
APPENDIX

Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette-Guérin-Unresponsive High-Risk Non-Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (Jacobj@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

RESULTS (5/5)

FIGURE 4: CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶



^aOverall CR rate is based on CR at any time. ^bThe efficacy analysis was performed on all treated patients who had active disease at baseline and adequate disease assessment post baseline or who had progressed, died due to recurrence of HR disease, or discontinued the study. ^cA CR is defined as having a negative cystoscopy and negative (including atypical) centrally read urine cytology or positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative (including atypical) centrally read cytology at any time point. CIS, carcinoma in situ; CR, complete response; HR, high risk; NMIBC, non-muscle-invasive bladder cancer.

NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility for RC

FIGURE 3
Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

APPENDIX



Reasons for Refusal of or Ineligibility for Radical Cystectomy in Patients With Bacillus Calmette–Guérin-Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer From the SunRISe-1 Study

Joseph M Jacob (JacobJ@upstate.edu),¹ Felix Guerrero-Ramos,² Evangelos Xylinas,³ Giuseppe Simone,⁴ Yair Lotan,⁵ Christopher Pieczonka,⁶ Harm Arentsen,⁷ Andrea Necchi,⁸ Girish Kulkarni,⁹ Manish I Patel,¹⁰ David Cahn,¹¹ Jong Kil Nam,¹² Martin Bögemann,¹³ Shalaka Hampras,¹⁴ Katherine Stromberg,¹⁴ Jason Martin,¹⁵ Abhijit Shukla,¹⁶ Hussein Sweiti,¹⁷ Michiel van der Heijden¹⁸

APPENDIX

REFERENCES:

1. NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 3.2023. <https://jnccn.org/view/journals/jnccn/18/3/article-p329.xml>. 2. Gontero P, et al. EAU guidelines on non-muscle-invasive bladder cancer (TaT1 and CIS). https://d56bochluxqz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Non-muscle-Invasive-Bladder-Cancer-2023_2023-03-10-101110_jued.pdf. 3. Musat MG, et al. *Clinicoecon Outcomes Res*. 2022;14:35-48. 4. Daneshmand S, et al. *Urol Oncol*. 2022;40:344.e1-344.e9. 5. Daneshmand S, et al. Presented at AUA 2023; April 28-May 1, 2023; Chicago, IL, USA. 6. Necchi A, et al. Presented at ESMO 2023; October 20-24, 2023; Madrid, Spain. 7. DeAngelis N, et al. *Cancer Chemother Pharmacol*. 2022;89:515-527.

DISCLOSURES:

Dr Jacob reports consulting or advisor fees from Janssen, Urogen, Verity Pharmaceuticals, and Photocure.

ACKNOWLEDGMENTS:

We thank the patients who participated in the study, their families, and the investigators and clinical research staff from the study centers. This study was sponsored by Janssen Research & Development. Editorial support was provided by Shivani Vaidya, PharmD, and Benjamin Ricca, PhD, of Parexel and funded by Janssen Global Services, LLC.

NAVIGATION



KEY TAKEAWAYS

CONCLUSIONS

INTRODUCTION

METHODS

FIGURE 1
Study design

RESULTS

TABLE 1
Patient characteristics

FIGURE 2
Reasons for refusal of and ineligibility for RC

FIGURE 3
Reasons for refusal of cystectomy by age, sex, and nicotine status

FIGURE 4
CR rate^a in patients with HR NMIBC CIS (Cohort 2)⁶

APPENDIX

