CREST Physician Experience Survey—Evaluating the Impact of Time and Effort of Treatment Administration in Non-Muscle Invasive Bladder Cancer (NMIBC)

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Conclusions

- Despite a small sample size, our findings suggest that among specialists, urologists will continue to lead diagnosis and treatment selection in high-risk (HR)-NIMBC.
- Overall, subcutaneous (SC) sasanlimab plus Bacillus Calmette-Guerin (BCG) was easier to administer and required less effort to schedule compared with intravenous (IV) programmed cell death-ligand 1 (PD-[L]1) inhibitor plus BCG; the management of adverse events (AEs) were similar for both therapies.
- Total treatment time was notably lower for SC sasanlimab plus BCG compared with IV PD-(L)1 inhibitor plus BCG, and respondents expect estimated total administration time to be shorter with SC sasanlimab in the real-world setting compared with a clinical trial.
- Pending approval, SC sasanlimab may offer a quicker, more convenient treatment option versus other IV administered treatments, and potentially save time, effort, and resource costs for healthcare systems.

Background

- Bladder cancer is one of the most common types of cancer worldwide, with more than 600,000 cases reported in 2022[1]; approximately 75% of cases are NMIBC at diagnosis,[2] among which, a substantial portion are classified as HR.[3]
  - A retrospective analysis of 1621 patients with NMIBC suggests that approximately 45% of patients are classified as HR according to the European Association of Urology risk stratification.[3]
- The standard of care for HR-NMIBC is transurethral resection of the bladder tumor (once per week for 6 weeks) followed by intravesical BCG induction (6 weekly doses) and 1–3 years of maintenance BCG.[4]
  - Approximately 40% of patients experience disease progression or recurrence at 24 months, with unfavorable prognosis and limited treatment options.[5-7]
- Sasanlimab, a new SC programmed cell death protein 1 (PD-1) inhibitor, with BCG is in development for the treatment of BCG-naive HR-NMIBC (CREST trial, NCT04165317).[8]
  - Sasanlimab with BCG induction and maintenance was found to prolong event-free survival with a hazard ratio of 0.68.[8]
- We surveyed CREST investigators, who were familiar with BCG and sasanlimab and who may also have had experience with IV PD-(L)1 inhibitor therapy from other investigational trials.
- The primary objective was to better understand the time and effort required to treat HR-NMIBC with BCG and either SC sasanlimab or an IV PD-(L)1 inhibitor, particularly in terms of treatment setting and healthcare professional involvement.

Methods

- An online survey was conducted among principal investigators who had treated ≥3 patients with BCG only and ≥3 patients with combination SC sasanlimab and BCG.
- Survey questions were developed via five 60-minute cognitive interviews with 4 urologists and 1 oncologist conducted between April 24, 2023, and May 5, 2023.
- A 23-item online survey available between June 2023 and December 2024, distributed in 6 languages to active investigators, covered questions on diagnosis, treatment selection, and management across both clinical trial and real-world settings.
- Findings were reported for SC sasanlimab plus BCG and IV PD-(L)1 inhibitor plus BCG. BCG monotherapy is provided, where appropriate, to provide proper context.

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Results

- Globally, 25 investigators (20 urologists and 5 oncologists) participated in the survey; of these, 16 had experience with IV PD-(L)1 inhibitor (**Table 1**).
  - Respondents were enrolled from 10 different countries, and most (60%) held positions at academic/teaching hospitals.

Table 1. Population Demographics

Demographic	n (N=25)
Specialties	
Urology	20
Oncology	5
Countries*	
Europe	16
United States	6
Other	3
Position	
Academic/teaching hospital	15
Private practice/clinic	9
Nonacademic hospital	1
Average years in practice	15

*Europe includes France (n=2), Germany (n=2), Italy (n=1), Poland (n=3), Spain (n=5), and United Kingdom (n=3); Other includes Australia (n=1), Canada (n=1), and Republic of Korea (n=1).

- Among respondents (N=25), urologists were identified as the primary decision-makers for both patient diagnosis (93%) and treatment selection (81%), whereas oncologists played a lesser role (7% for each).
- In a real-world setting, urologists and urology nurses are expected to treat and manage a majority of NMIBC, with medical assistants, nurse practitioners, and physician assistants also having a greater role in routine care, patient support, and administrative tasks outside of a clinical trial (**Table 2**).

Table 2. Roles Involved in Disease and Treatment Management* of HR-NMIBC†

Role	Time in Clinical Trial (Mean), % n=25	Time Outside Clinical Trial (Mean), % n=24‡
Urologist	48	68
Urology nurse	20	26
Oncologist	17	14
Clinical coordinator	13	0
Oncology nurse	12	7
Infusion nurse	10	8
Medical assistant	4	8
Nurse practitioner	3	6
Physician assistant	1	9
Other	0	0

HR-NMIBC, high-risk nonmuscle invasive bladder cancer.
Light blue, increase ≥3%; yellow, neutral 2%; red, decrease ≥3% relative to clinical trial.
*Time involved with ongoing treatment, administration, and patient management of patients with HR-NMIBC.
†When multiple roles share responsibilities or contribute to the same outcome, the sum of their individual percentage contributions can exceed 100%.
‡Data of 1 individual were removed because they indicated involvement of a clinical coordinator in the same capacity as during a clinical trial and were therefore considered inaccurate.

- For the administration of SC sasanlimab and IV PD-(L)1 inhibitor therapy, the role of healthcare professionals varied, with nurses expected to have a greater role outside of a clinical trial (**Table 3**).

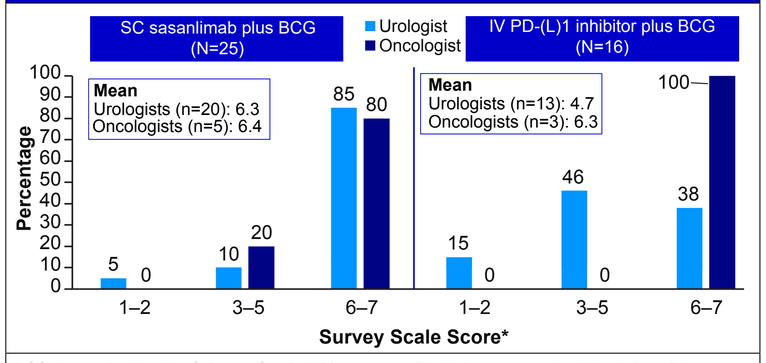
Table 3. Practitioner Roles Involved in Administering Therapy in the Clinical Trial and Real-World Setting*

Role	Clinical Trial, %			Real World,† %		
	SC sasanlimab, (n=25)	IV PD-(L)1 inhibitor, (n=16)	BCG mono-therapy, (n=25)	SC sasanlimab, (n=22)	IV PD-(L)1 inhibitor, (n=13)	BCG mono-therapy, (n=22)
Oncologist	**18**	**26**	4	15	**31**	3
Urologist	**37**	**27**	**45**	**35**	25	**45**
Nurse practitioner	4	3	4	5	4	5
Oncology nurse	14	18	**11**	**21**	**26**	**12**
Urology nurse	**19**	8	**38**	**24**	5	**40**
Infusion nurse	9	**28**	1	10	**35**	1
Physician assistant	0	0	4	0	0	9
Clinical coordinator	10	9	7‡	0	0	0‡
Medical assistant	1	0	3	5	0	6
Other	0	0	0	0	0	0

BCG, Bacillus Calmette-Guerin; IV, intravenous; PD-(L)1, programmed cell death-ligand 1; SC, subcutaneous.
Bolded values represent the top 3 roles for each treatment and setting. Light blue, increase ≥3%; yellow, neutral 2%; red, decrease ≥3% relative to clinical trial.
*When multiple roles share responsibilities or contribute to the same outcome, the sum of their individual percentage contributions can exceed 100%.
†Respondent estimates of practitioner roles in real-world setting. Data of 3 individuals were removed because they indicated involvement of a clinical coordinator in the same capacity as during a clinical trial and were therefore considered inaccurate.
‡Statistical significance between means, as determined by a paired t test with a 90% confidence interval and a significance level of 0.1.

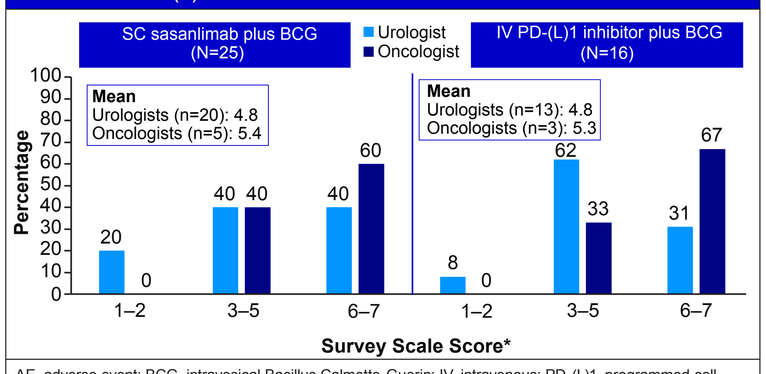
- Unlike this clinical trial setting in which patients are primarily treated in an academic setting, respondents expect a greater proportion of patients in the real-world setting to be treated with SC sasanlimab plus BCG in a community hospital or clinic.
- In general, 52% of respondents reported SC sasanlimab plus BCG required little to no effort to schedule a patient, whereas 88% of respondents found IV PD-(L)1 inhibitor plus BCG required moderate to significant effort to schedule.
- Urologists found that administering SC sasanlimab plus BCG was easier than administering IV PD-(L)1 inhibitor plus BCG, whereas oncologists found that administering IV PD-(L)1 inhibitor plus BCG or SC sasanlimab plus BCG was similar (**Figure 1**).
- Overall ease of AE management was similar for both treatments (**Figure 2**).

Figure 1. Ease of Experience by Specialty in Administering SC Sasanlimab Plus BCG and IV PD-(L)1 Inhibitor Plus BCG in a Clinical Trial



BCG, intravesical Bacillus Calmette-Guerin; IV, intravenous; PD-(L)1, programmed cell death-ligand 1; SC, subcutaneous.
*1=extremely difficult and 7=extremely easy.

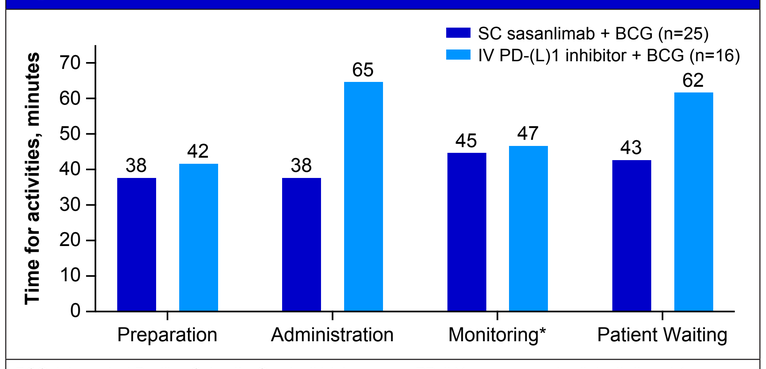
Figure 2. Ease of AE Management by Specialty for Sasanlimab Plus BCG or IV PD-(L)1 Inhibitor Plus BCG in a Clinical Trial



AE, adverse event; BCG, intravesical Bacillus Calmette-Guerin; IV, intravenous; PD-(L)1, programmed cell death-ligand 1; SC, subcutaneous.
*1=extremely difficult and 7=extremely easy.

- In the clinical trial setting, total administration time with BCG, which included preparation, administration, post-treatment monitoring, and waiting times, was shorter with SC sasanlimab (mean, 164 minutes) than with IV PD-(L)1 inhibitor (mean, 216 minutes; **Figure 3**).

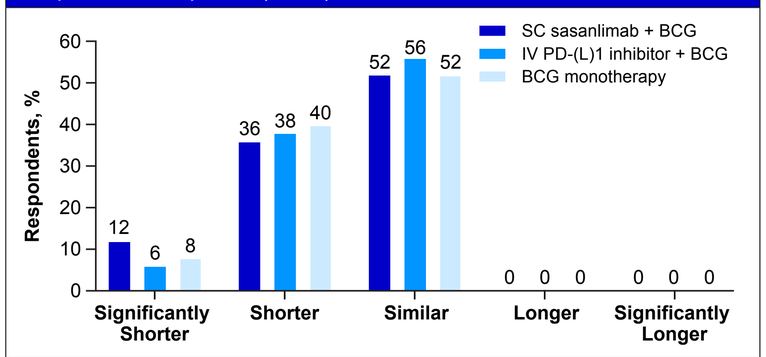
Figure 3. Administration Time Within a Clinical Trial



BCG, intravesical Bacillus Calmette-Guerin; IV, intravenous; PD-(L)1, programmed cell death-ligand 1; SC, subcutaneous.
*Monitoring after treatment.

- Estimated administration time in real-world settings is expected to be shorter than in a clinical trial, with a greater reduction for SC sasanlimab (48% of respondents) than with IV PD-(L)1 inhibitor (44% of respondents; **Figure 4**).

Figure 4. Total* Expected Time Required Outside a Clinical Trial Per Respondent Response (N=25)



BCG, intravesical Bacillus Calmette-Guerin; IV, intravenous; PD-(L)1, programmed cell death-ligand 1; SC, subcutaneous.
*Includes preparation, administration, posttreatment monitoring, and waiting times.