SunRISe-1 Cohort 4: A Phase 2, Randomized, Open-Label Study of TAR-200 Monotherapy in BCG-Unresponsive HR NMIBC Patients With Papillary Only Disease





5 (9.6)

4 (7.7)

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3 (5.8)

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- The most frequent Grade ≥3 TRAE was bladder pain
- 5.8% (n=3) had ≥1 serious TRAEs⁺⁺
- 7.7% (n=4) had TRAEs that led to treatment discontinuation^{‡‡}
- No treatment-related deaths reported

Johnson &Johnson

Nocturia

Pruritus

Asthenia

Pelvic pain

Bladder spasm

Noninfective cystitis

Bladder irritation

Urinary tract pain

Urinary incontinence

*Patients with BCG-urresponsive papillary-only HR NMIBC (high-grade Ta, any Ti) per protocol amendment 4. Yan event is defined as recurrence, progression, or death. *Safety is shown for all patients who received at least 1 does of TAR-200 in the safety analysis set (N+52). Yan AE was categorized as related if the investigator determined that there was a possible, probable, or causal relationship between the AE and TAR-200 or the insertion or removal procedure or urinary placement cathed. *Tigetoretic in 55% of patients. Where AE is a constrained that there was a possible, probable, or causal relationship between the AE and TAR-200 or the insertion or removal spatients may have had 1 Grade 33 TRAE. *Tincluded 1 event each of sepsis, urinary tract infection in spinal fracture. Note, patients may have had 1 Grade 33 TRAE. *Tincluded 1 event each of sepsis, urinary tract infection in spinal fracture. Note, patients may have had 1 Grade 33 TRAE. *Tincluded 1 event each of sepsis, urinary tract infection in spinal fracture. TRAE AE, advaete event; TRAE, Seisene - Green aurival; FED, Seisene Cooperative Oncology Group performance status; HRAD, health-related quility of fire KE, not estimable; HR NMIEC, high risk non-muscle-invasive bladder cancer, 03, overall aurival; FPS, disease-free aurival; FED, Satesten Cooperative Oncology Group performance status; HRAD, health-related quility of fire KE, not estimable; HR NMIEC, high risk non-muscle-invasive bladder L Grindering DC, et al. *Eur Und Focus*, 2000;6620-6022, Pome-Faudoa FP, et al. Biomed Microderices. 2019;21:47:3 a Duta on FIE. Janese Scientific Alfans, LLC. TAR-200 Draft Presenbing Information. 4. Clinicatrialistic, VAC essent April, PC, 2000;21:47:3 a Duta on FIE. Janese Scientific Alfans, LLC. TAR-200 Draft Presenbing Information. 4. Clinicatrialistic, VAC essent April, PC, Satester, Claude Microderices. 2019;21:47:3 duta 0:202. Oral presentation.

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