Efficacy and Safety of Bleselumab in Kidney Transplant Recipients: A Phase 2, Randomized, Open-Label Study

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Session Information

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Session Name: Concurrent Session: Kidney Immunosuppression: General Considerations - 2

Session Time: 4:30pm-6:00pm

└ **Presentation Time:** 4:54pm-5:06pm

Location: Room 6A

Related Abstracts

Prolonged-Release Tacrolimus Dosing in *De Novo* Kidney Transplantation: Randomized, Open-Label, Pilot Study

Extended-Release Tacrolimus Plus Everolimus vs Extended-Release Tacrolimus Plus Micophenolate Mofetil in Primary Deceased Donor Kidney Transplant Recipients: 1-Year Results of an Open Label, Randomized Phase 2 Clinical Trial

Introduction: Bleselumab (ASKP1240) is an anti-CD40 monoclonal antibody currently in development. This phase 2, randomized, open-label study assessed the efficacy and safety of bleselumab in *de novo* kidney transplant recipients over 36 months post-transplant (NCT01780844).

Methods: Transplant recipients were randomized (1:1:1) to:

[middot] Standard of care (SoC) with immediate-release tacrolimus (IR-T; 0.1 mg/kg/day; target C_{trough} 4–11 ng/mL) + mycophenolate mofetil (MMF; 1 g twice daily)

[middot] Bleselumab (200 mg on Days 0/7/14/28/42/56/70/90, and monthly thereafter) + IR-T (0.1 mg/kg/day; target C_{trough} 4–11 ng/mL days 0–30, then 2–5 ng/mL)

[middot] Bleselumab (dosing regimen as per bleselumab + IR-T group) + MMF

All received basiliximab induction (20 mg injection pre-transplant and on Day 3–5 post-transplant) and corticosteroids. The primary endpoint was incidence of biopsy-proven acute rejection (BPAR; Banff grade ≥1) through month 6. Treatment-emergent adverse events (TEAEs) were assessed to 6 months post-transplant; serious TEAEs were recorded for 36 months.

Results: 149 patients were randomized: 138 received ≥1 dose of study drug (SoC [n=48]; bleselumab + IR-T [n=44]; bleselumab + MMF [n=46]). Bleselumab + IR-T treatment demonstrated noninferiority with SoC: at 6 months post-transplant, BPAR incidence was 3 (6%) for SoC, 4 (9%; P=0.706 vs SoC) for bleselumab + IR-T, and 17 (37%; P<0.001 vs SoC) for bleselumab + MMF; at 36 months, BPAR incidence was 6 (13%), 5 (11%; P=1.000), and 19 (41%; P=0.002), respectively. 138 transplant recipients experienced a TEAE during the 6-month treatment period. The bleselumab + MMF group had a higher incidence of serious TEAEs and TEAEs leading to treatment discontinuation compared with the bleselumab + IR-T group. Both groups had greater incidences of drug-related TEAEs and TEAEs leading to treatment discontinuation compared with SoC. There were 4 deaths (2 per bleselumab group) during this study, none deemed related to bleselumab.

Conclusions: Treatment with bleselumab + IR-T over 36 months demonstrated similar efficacy in the prevention of BPAR compared with SoC. No new safety signals were observed.

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