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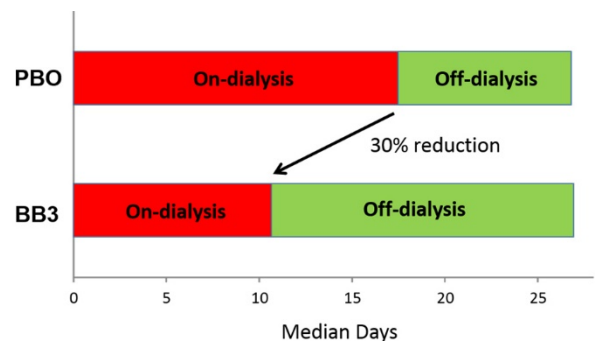
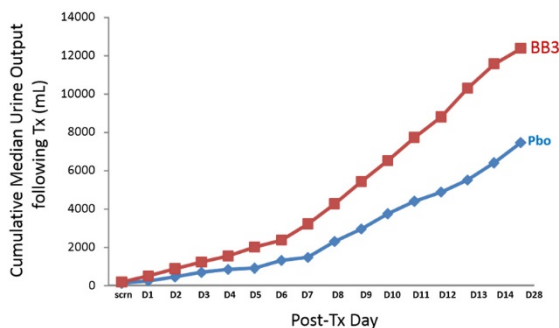
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**BB3, a Hepatocyte Growth Factor-like Small Molecule, Improves Outcome in Kidney Transplant Recipients with Delayed Graft Function**

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**Background:** Duration of delayed graft function (DGF) portends poor short and long-term renal function and graft survival. We studied the safety and efficacy of BB3, a small molecule with HGF-like activities, dosed starting 24 hr post-transplant (Tx) in patients with reduced urine output (UO) in a double-blind Phase 2 study. Methods: Patients producing <50 cc urine/hr over 68 h post-Tx were randomized (2:1) to BB3 (2 mg/kg IV QD X 3 d) or placebo (PBO). An interim analysis was performed on 12 BB3 and 7 PBO-treated patients.

**Results:** BB3 was safe and well-tolerated. BB3 reduced the median time to produce 1.2L UO/24 hr from > 28 d to 7.5 d, increased the % of patients reaching this UO within 28 d from 43% to 83%, increased cumulative UO (figure), decreased median duration of dialysis (figure), decreased % on dialysis days during Days 7-28 (14.2% to 7.1%) and during Days 14-28 (10.9% to 3.6%), reduced median SCr, reduced BUN, and shortened median hospital stay (7 d to 5.5 d). BB3 reduced serum CRP and NGAL.



**Conclusions:** BB3 administered ~24 hours post-Tx significantly reduced severity of DGF in patients presenting with reduced UO. Confirmation of these results in a Phase 3 trial may translate to improved long-term outcome, decreased Tx costs, increased use of marginal organs, and a shorter waitlist.