

Table S1: Key exclusion criteria

- Multi-organ transplant (eg, kidney-pancreas)
- previous transplant with any nonrenal organ
- Previous graft loss due to immunological reasons in the first posttransplant year
- Nonheart beating donor, ABO incompatible transplant
- Panel reactive antibody (PRA) level >20% within the 4 months prior to enrollment
- Preexisting human leukocyte antigen (HLA) donor specific antibodies
- Platelets <100 000/mm³ with absolute neutrophil count <2000/mm³ or leukocytes <3000/mm³
- Hemoglobin <8 g/dL
- Donor positive for hepatitis B surface Antigen (HBsAg) or hepatitis C virus (HCV)
- Recipient positive for HBsAg and/or HCV with abnormal liver enzymes
- Severe liver disease
- Hypersensitivity against either tacrolimus or mycophenolic acid

Table S2: Observed, nondose-normalized tacrolimus pharmacokinetic parameters in de novo kidney transplant patients randomized to TacHexal or Prograf (pharmacokinetic population)

	Day 3				Day 10				Month 1			
	TacHexal		Prograf			TacHexal		Prograf		TacHexal		Prograf
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Dose, mg/day	29	11.6 (3.7)	35	12.6 (3.7)	26	13.6 (5.0)	31	13.4 (3.4)	23	11.7 (4.2)	26	11.1 (3.2)
AUC ₀₋₁₂ (ng*h/mL)	20	161 (83)	19	186 (109)	20	163 (58)	19	140 (61)	23	210 (59)	21	208 (88)
C _{max} (ng/mL)	29	33.7 (16.1)	35	25.8 (14.7)	26	29.8 (14.0)	31	24.3 (10.0)	23	34.6 (15.3)	26	32.8 (16.8)
C ₀ (ng/mL)	32	10.2 (8.3)	39	9.8 (5.3)	24	9.3 (5.8)	35	11.3 (7.1)	25	13.3 (8.7)	30	12.3 (4.9)

AUC, area under the curve; CI, confidence interval; C_{max}, peak concentration

Table S3: Adverse events occurring in >10% of patients in either group by month 6 posttransplant in de novo kidney transplant patients randomized to TacHexal or Prograf, n (%) (safety population)

	TacHexal (n=35)	Prograf (n=38)
Any adverse event	34 (97.1)	38 (97.4)
Anemia	4 (11.4)	7 (17.9)
Leukopenia	4 (11.4)	7 (17.9)
Nephrogenic anemia	5 (14.3)	2 (5.1)
Diarrhea	6 (17.1)	5 (12.8)
Constipation	2 (5.7)	6 (15.4)
Flatulence	3 (8.6)	4 (10.3)
Nausea	2 (5.7)	5 (12.8)
Peripheral edema	4 (11.4)	7 (17.9)
Kidney transplant rejection	3 (8.6)	6 (15.4)
Urinary tract infection	8 (22.9)	18 (46.2)
Cytomegalovirus infection	1 (2.9)	5 (12.8)
Wound complication	16 (45.7)	19 (48.7)
Complications of transplanted kidney	9 (25.7)	13 (33.3)
Renal lymphocele	4 (11.4)	3 (7.7)
Blood creatinine increased	6 (17.1)	7 (17.9)
Hyperkalemia	9 (25.7)	9 (23.1)
Hyperuricemia	3 (8.6)	9 (23.1)
Hypomagnesemia	5 (14.3)	7 (17.9)
Hypocalcemia	5 (14.3)	4 (10.3)
Hypokalemia	5 (14.3)	4 (10.3)
Vitamin D deficiency	2 (5.7)	6 (15.4)
Headache	4 (11.4)	1 (2.6)
Insomnia	4 (11.4)	6 (15.4)
Bladder pain	5 (14.3)	3 (7.7)
Renal hypertension	-	4 (10.3)
Hypertension	12 (34.3)	20 (51.3)

Table S4: Laboratory values at month 6 posttransplant in de novo kidney transplant patients randomized to TacHexal or Prograf (safety population). Values are shown as mean (SD)

	TacHexal (n=35)	Prograf (n=39)
Hemoglobin, g/dL	12.9 (2.1)	12.8 (1.5)
Leukocytes, × 10 ⁹ /L	7.0 (3.5)	6.1 (2.6)
Platelets, × 10 ⁹ /L	226 (62)	224 (68)
Serum creatinine, µmol/L	138 (56)	162 (62)
Urine protein, mg/mL	0.5 (1.5)	0.2 (0.1)
Alanine aminotransferase, U/L	28.9 (16.4)	28.4 (41.5)
Aspartate aminotransferase, U/L	24.3 (8.7)	25.3 (14.5)
Blood glucose, mmol/L	6.2 (2.8)	5.8 (1.0)
HbA1c (%)	6.0 (1.2)	5.8 (0.9)
Total cholesterol, mmol/L	5.3 (1.1)	5.3 (1.3)
LDL-cholesterol, mmol/L	3.2 (1.0)	3.2 (1.1)
HDL-cholesterol, mmol/L	1.3 (0.4)	1.3 (0.6)
Triglycerides, mmol/L	2.1 (0.9)	2.2 (1.7)