

Electronic Supplementary Table Studies Included in Pooled Safety Analysis

Study number	ClinicalTrials.gov identifier	Phase	Study design	Duration of treatment	Treatments	N
MKC-TI-009	NCT00308308	3	Multicenter, open label, randomized, controlled, in patients with T1DM	12 months	TI vs SC insulin, each in combination with insulin glargine	589
MKC-TI-030	NCT00308737	3	Multicenter, open label, randomized, in patients with T1DM or T2DM	24 months	TI or usual care	2053
MKC-TI-101	NCT00539396	2	Multicenter, open label, randomized, in patients with T1DM	12 weeks	TI vs insulin aspart, each in combination with insulin glargine	120
MKC-TI-117	NCT00700622	3	Multicenter, open label, randomized, in patients with T1DM	16 weeks	TI vs insulin lispro, each in combination with insulin glargine	130
MKC-TI-171	NCT01445951	3	Multicenter, open label, randomized, forced titration, in patients with T1DM	24 weeks	TI vs insulin aspart, each in combination with SC basal insulin	518
MKC-TI-005	NCT00511732	2	Double blind, randomized, placebo controlled, forced titration, in patients with T2DM	18 weeks	TI vs TP	227
MKC-TI-014	NCT00539890	3	Multicenter, open label, randomized, in patients with T2DM	6 months ^a	TI vs rapid-acting insulin, each in combination with insulin glargine	309
MKC-TI-026	NA	2	Multicenter, open label, randomized in patients with T2DM	12 weeks	TI in combination with oral antidiabetic vs usual care	90
MKC-TI-102	NCT00309244	3	Multicenter, open label, randomized, controlled, in patients with T2DM	12 months	TI plus insulin glargine vs premixed insulin	677
MKC-TI-103	NCT00332488	3	Multicenter, open label, randomized, controlled, in patients with T2DM suboptimally controlled on metformin and a secretagogue	24 weeks	TI in combination with metformin, or TI alone vs metformin and a secretagogue	528
PDC-INS-0008	NCT00511602	2	Double blind, randomized, placebo controlled, in patients with T2DM	12 weeks	TI vs TP	126
MKC-TI-175	NCT01451398	3	Multicenter, double blind, randomized, placebo controlled, in insulin-naïve patients with T2DM suboptimally controlled on MTD of metformin or MTD of metformin and 1-2 OADs	24 weeks	TI vs TP	354
MKC-TI-162 ^b	NCT01196104	3	Multicenter, open label, randomized, forced titration, in patients with T2DM	16 weeks	TI vs insulin aspart, each in combination with insulin glargine	39

MTD maximum tolerated dose, *NA* not applicable, *OAD* oral antidiabetic drug, *SC* subcutaneous, *T1DM* type 1 diabetes mellitus, *T2DM* type 2 diabetes mellitus, *TI* Technosphere Insulin, *TP* Technosphere inhalation powder without insulin (placebo)

^aOnly the first 6-month treatment period data are included in the pooled analyses. During the remaining period, patients were off study treatment

^bA substudy of MKC-TI-162 (MKC-TI-164) evaluated and compared changes in pulmonary function