

Session GPS02 - Sunday General Poster Session

Itinerary

1181-P / 1181 - Assessing the Safety of Sitagliptin in Patients with Type 2 Diabetes and Chronic Kidney Disease in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS)

June 12, 2016, 12:00 PM - 2:00 PM

Poster Hall (Halls D-E)

Authors

SAMUEL S. ENGEL, SHAILAJA SURYAWANSHI, ROBERT G. JOSSE, ERIC PETERSON, RURY R. HOLMAN, TECOS STUDY GROUP, *Kenilworth, NJ, Toronto, ON, Canada, Durham, NC, Oxford, United Kingdom*

Disclosures

S.S. Engel: *Employee; Author*; Merck & Co., Inc. *Stock/Shareholder; Author*; Merck & Co., Inc. S. Suryawanshi: *Employee; Author*; Merck & Co., Inc. *Stock/Shareholder; Author*; Merck & Co., Inc. R.G. Josse: *Research Support; Author*; Amgen Inc., AstraZeneca, Boehringer Ingelheim Pharmaceuticals, Inc., Eli Lilly and Company, Janssen Pharmaceuticals, Inc., Merck & Co., Inc. E. Peterson: *Consultant; Author*; AstraZeneca, Bayer HealthCare, Sanofi U.S., Janssen Pharmaceuticals, Inc.. *Research Support; Author*; Janssen Pharmaceuticals, Inc., Eli Lilly and Company. R.R. Holman: *Consultant; Author*; Amgen Inc., Bayer HealthCare, Merck & Co., Inc, Intarcia Therapeutics, Inc., Novartis AG, Novo Nordisk Inc. *Research Support; Author*; Merck & Co., Inc, Bayer HealthCare, AstraZeneca. *Other Relationship; Author*; GlaxoSmithKline, Janssen Pharmaceuticals, Inc., Takeda Pharmaceutical Company Limited.

TECOS, a randomized, double-blind, placebo-controlled trial that assessed the impact of sitagliptin on cardiovascular outcomes, provides an opportunity to examine comparative safety-related outcomes in patients with type 2 diabetes (T2DM) and chronic kidney disease (CKD) defined as an eGFR <60 ml/min/1.73m².

TECOS included 3,324 CKD patients (1,667 sitagliptin, 1,657 placebo) with mean (SD) age 68.8 (7.9) years and diabetes duration 13.7 (9.0) years; 62% were male. Over ~2.8 median years' follow-up, sitagliptin-assigned patients, compared with placebo-assigned patients, had generally similar rates of diabetic eye disease, diabetic neuropathy, renal failure, malignancy, bone fracture and pancreatitis (Table). The incidence of hypoglycemia requiring assistance was 3.4% and 3.3% in the sitagliptin and placebo groups, respectively.

In TECOS, no specific safety concerns were identified with the use of sitagliptin in T2DM patients with CKD.

Proportions of CKD patients in TECOS with:	Sitagliptin	Placebo
	N=1667	N=1657
Any diabetes complication	40.1%	42.1%
Diabetic eye disease	3.1%	3.1%
Diabetic neuropathy	3.9%	3.6%
Renal failure	3.3%	3.6%
Malignancy	4.3%	5.1%
Bone fracture	3.7%	3.3%
Pancreatitis	0.1%	0.1%