

**EFFICACY AND SAFETY OF ORMD-0801(INSULIN CAPSULES) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS INADEQUATELY CONTROLLED WITH METFORMIN OVER 28 DAYS: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY**

R. Eldor<sup>1</sup>, J. Neutel<sup>2</sup>, K. Homer<sup>3</sup>, M. Kidron<sup>4</sup>

<sup>1</sup>*Diabetes Unit, Institute for Endocrinology, Metabolism and Hypertension, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel*

<sup>2</sup>*OCRC, Tustin, California, USA*

<sup>3</sup>*Integrium, LLC, Tustin, California, USA*

<sup>4</sup>*Oramed Pharmaceuticals, Jerusalem, Israel*

Insulin therapy is limited by the need for injections and a narrow therapeutic index. Here we report the results from a Phase 2b placebo controlled study, of ORMD-0801 16 mg or 24mg oral insulin for 28 days in patients with T2DM. Eligible patients with T2DM were randomized 1:1:1 to receive placebo, ORMD-0801 16 mg insulin or 24 mg. The primary endpoint was change from baseline in weighted mean night-time glucose levels (defined as 6 hours after treatment) based on two nights of continuous glucose monitoring (CGM). A total of 179 patients completed the study. Enrolled patients were ~ 57.7 years old and had a HbA1c of ~8% and FPG of ~160mg/dl. The primary endpoint of %change from baseline of weighted mean night-time CGM (80% trimmed data) was significantly better in patients treated with ORMD-0801 (combined dose group) than placebo [2.01% and 8.48%, respectively;  $p = 0.03$ ; mean change from baseline (mg/dL) was  $1.7 \pm 23.5$  and  $13.7 \pm 26.1$ , respectively;  $p = 0.0120$ ]. The actual difference between other parameters of glycemic control obtained by CGM (including mean 24-hour CGM glucose, mean fasting CGM glucose, mean daytime CGM glucose and mean fasting CGM glucose significantly improved with ORMD-0801. HbA1c with ORMD-0801 combined group was significantly better than placebo (-0.01 and 0.20%, respectively;  $p = 0.0149$ ). ORMD-0801 was safe and well tolerated. In conclusion, ORMD-0801 administered at bedtime was safe and resulted in lower mean night-time glycemia, mean 24-hour glycemia and HbA1c.