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Oramed, Medpace CRO join hands for oral insulin trial

October 8, 2012 | News | By BioSpectrum Bureau

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Singapore: Oramed Pharmaceuticals subsidiary signed an agreement to retain Medpace as the clinical research organization (CRO) for Oramed's upcoming phase II clinical trial on its oral insulin capsule, ORMD-0801.

The FDA-approved trial will assess the safety and efficacy of Oramed's oral insulin in 147 patients at multiple centers across the US. Oramed plans to file an investigative new drug application (IND) with the FDA in this quarter and commence the trial following approval of the IND.

Medpace is led by top therapeutic and regulatory experts with comprehensive experience in the advancement of pharmaceutical agents for use in multiple therapeutic specialties, and will oversee the entire operation and data management of Oramed's phase II clinical trial. Dr David Orloff, VP, medical and regulatory affairs, Medpace, is playing a major role in the design and implementation of the upcoming trial.

Dr Orloff is a former director of the FDA's Division of Metabolism and Endocrinology Products and, with Medpace's exemplary standards as a CRO, is well-positioned to advance the most efficient and cost-effective path to drug approval for Oramed.

"We are excited about this collaboration, which represents a significant milestone for the company," commented Dr Nadav Kidron, CEO, Oramed. "After much due diligence, we decided to join forces with the experts at Medpace and we look forward to working with them on the FDA-approved clinical trial of our oral insulin capsule."