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GENEREX BIOTECHNOLOGY CORPORATION

Premeal Oral Insulin Rivaled Injectable Form in Small Study

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TORONTO — A formulation of insulin that is sprayed in the mouth and absorbed buccally seems to control glucose as well as injected insulin when used before a meal, Dr. Gerald Bernstein reported at the joint annual meeting of the Canadian Diabetes Association and the Canadian Society of Endocrinology and Metabolism.

The product, Generex Oral-lyn, is manufacturered by the Toronto-based company Generex Biotechnology.

When sprayed into the mouth using the company's RapidMist device, the insulin is absorbed into the buccal epithelium and is dispersed directly into the vascular system, thereby avoiding the problem of digestion that would occur if insulin were swallowed.

Dr. Bernstein, the company's vice president for medical affairs, presented a 3-month interim analysis of a 6-month study by Dr. Jaime Guevara-Aguirre and his associates at the Institute of Endocrinology IEMYR in Quito, Ecuador, where the product has been approved for use for patients with type 1 and type 2 diabetes.

First, 24 adolescents (mean age 15 years) and 5 young adults (21 years) with type 1 diabetes were stabilized for 6 weeks with basal twice-daily glargine and premeal injections of regular insulin.

For the next 6 weeks, they took Ora-lyn immediately before and after lunch rather than the injected regular insulin, while still injecting the glargine twice daily and the regular insulin before breakfast and dinner.

Patients could take the entire dose before the meal, because the timing of its action is similar to that of currently available short-acting analogues.

At baseline, the group had a mean hemoglobin A_{1c} of 9.9% and mean glucose of 236.6 mg/dL. After stabilization, their mean A_{1c} level had dropped to 8.4% and mean glucose (measured by the patients six times a day) to 140.4 mg/dL. After 3 weeks of substituting Ora-lyn for regular insulin at lunch, the mean A_{1c} was 8.5%, and mean glucose 143.3 mg/dL. Three weeks later (study week 12), the mean A_{1c} was 8.0%.

Doses of the glargine and the prelunch Oral-lyn were split in this study because previous data on each had shown that doing so improves efficacy. But in practice, piatients could take the entire dose of Ora-lyn before the meal, because the timing of its action is similar to that of available short-acting analogues: It begins working within 5 minutes, peaks at 30 minutes, and is cleared from the bloodstream by 2 hours. A larger study is underway to compare glargine plus either regular insulin or Ora-lyn given before each meal.

Generex Biotechnology plans to file a submission for approval in Canada and Europe concurrently in the next 12-15 months. Submission to the U.S. Food and Drug Administration is expected to follow and may fall within an 18-month time frame, according to a company spokesperson. ■

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