Lilly reports positive results for GIP/GLP-1 RA type 2 diabetes trial

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October 5, 2018

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Blood sugar readings on a glucose test device. Credit: Mike Mozart.

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Eli Lilly & Co.
Exhibit 2015
BPI Labs v. Eli Lilly
IPR2025-01346
Ex. 2015-001

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GIP/GLP-1 RA is a combination of both incretins in a single molecule and is intended to improve clinical benefits offered by a selective GLP-1 RA.

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The randomised, placebo-controlled Phase IIb type 2 diabetes trial assessed the efficacy of 1mg, 5mg, 10mg and 15mg doses of GIP/GLP-1 RA, compared to 1.5mg dulaglutide and placebo, in 300 patients over 26 weeks.

The primary objective of the trial was superiority of weekly GIP/GLP-1 RA over placebo in minimising HbA1c from baseline at 26 weeks.

GIP/GLP-1 RA's safety profile during the type 2 diabetes trial was found to be similar to the GLP-1 RA class. The most common side effects were gastrointestinal-related and dose-dependent.

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Lilly Diabetes product development vice-president Jeff Emmick said: "Despite the progress we've made in diabetes management, people living

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Lilly Diabetes product development vice-president Jeff Emmick said: "Despite the progress we've made in diabetes management, people living with type 2 diabetes often need additional treatments as their condition progresses.

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"We set a high bar for this Phase II study, and the results exceeded our expectations. We're excited to continue studying GIP/GLP-1 RA and hope to add it to our wide range of therapies for people with diabetes."

GIP/GLP-1 RA is being further investigated in the Phase III SURPASS clinical programme for type 2 diabetes patients. Lilly also plans to evaluate the use of GIP/GLP-1 RA for obesity and other disorders.

Lilly, in alliance with Boehringer Ingelheim, also reported full results from the CARMELINA trial that studied the long-term effect of Tradjenta on cardiovascular safety and kidney outcomes in 6,979 type 2 diabetes patients at high risk for heart and/or kidney disease.

The trial met its primary endpoint of a similar cardiovascular safety profile compared to placebo when added to standard of care.

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