

**GlucREG™**

Laboratory Experiments and Clinical Data Summary Report

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Released to: \_\_\_\_\_

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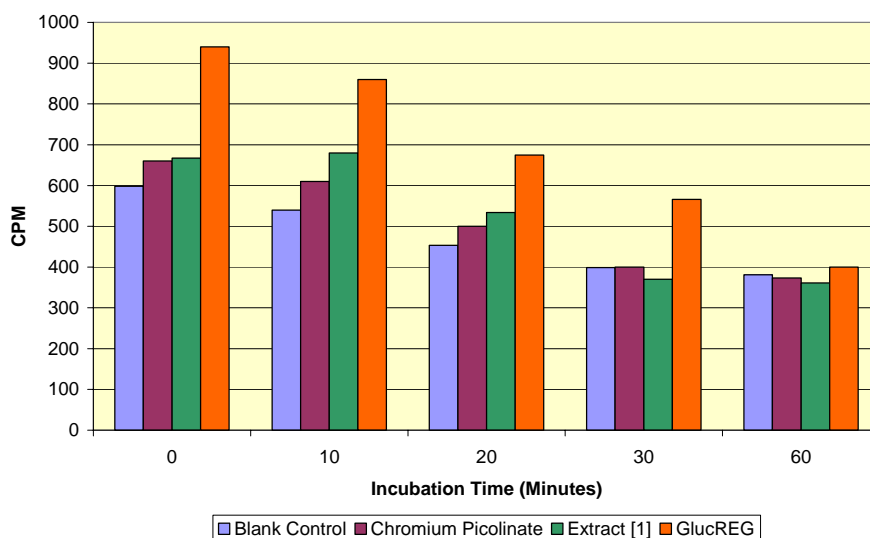
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## 1. In vitro Studies

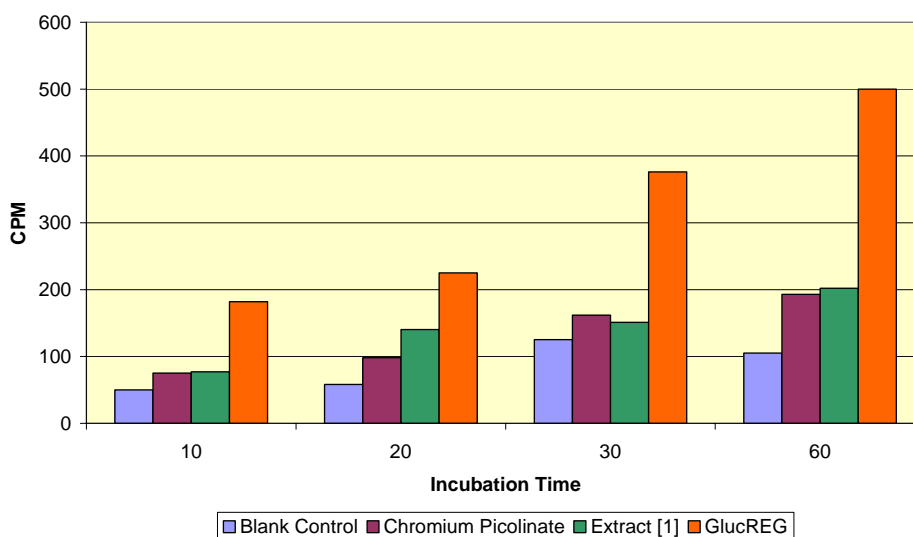
### (1) The Effects of GlucREG™ on Insulin binding and Internalization in Rat Skeleton Muscle Cells

Results:

**Fig. 1 Effects of GlucREG on Insulin Binding in Rat Muscle Cells**



**Fig. 2 Effects of GlucREG on Insulin internalization in Rat Muscle Cells**

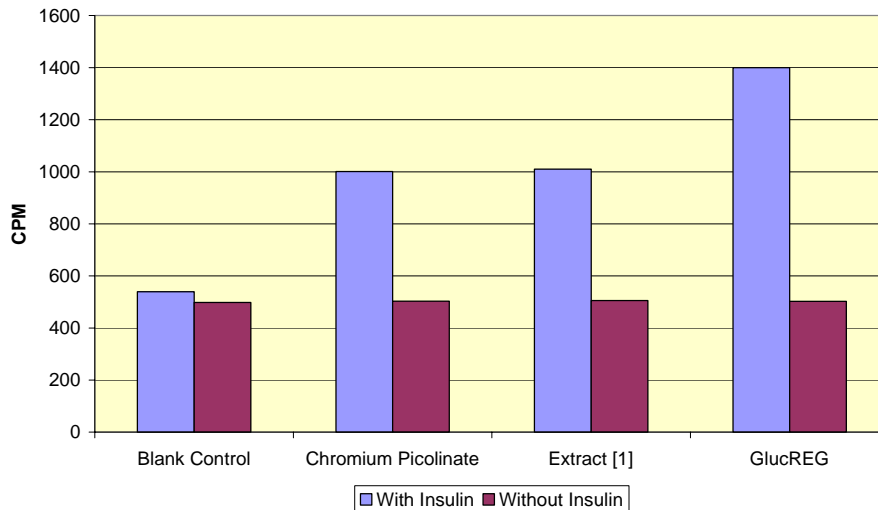


Results indicate that GlucREG™ significantly increases the insulin binding and internalization in muscle cells. The results are statistically significant ( $p < 0.001$ )

## (2) The Effects of GlucREG™ on Glucose Uptake in Rat Skeleton Muscle Cells

Results:

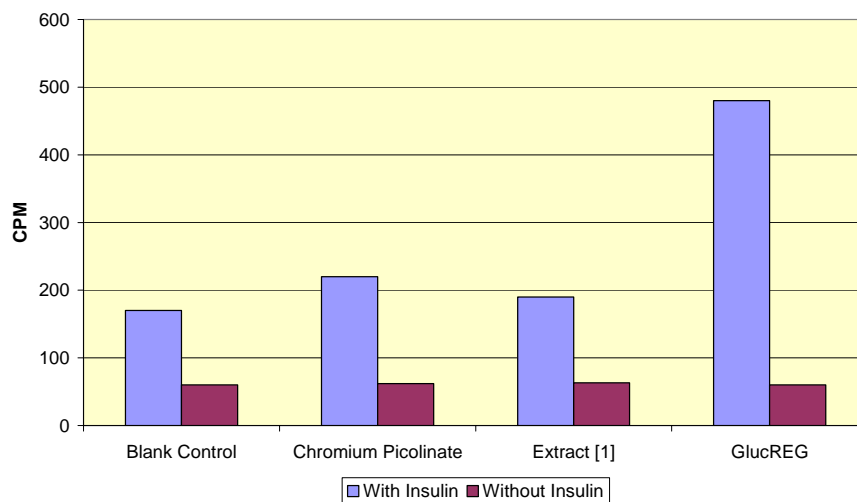
**Fig. 3 Effects of GlucREG on Insulin-Facilitated Glucose Uptake in Rat Muscle Cells**



Results indicate that GlucREG™ significantly enhances the effects of insulin to increase glucose uptake in muscle cells. Results indicate that muscle cells are sensitized to insulin.

## (3) The Effects of GlucREG™ on L-Leucine Uptake in Rat Skeleton Muscle Cells

**Fig. 4 Effects of GlucREG on Insulin-facilitated L-Leucine Uptake in Rat Muscle Cells**



Results indicate that GlucREG™ significantly enhances the effects of insulin to increase L-Leucine uptake in muscle cells. Results indicate that muscle cells are sensitized to insulin.

## 2. Clinical Studies

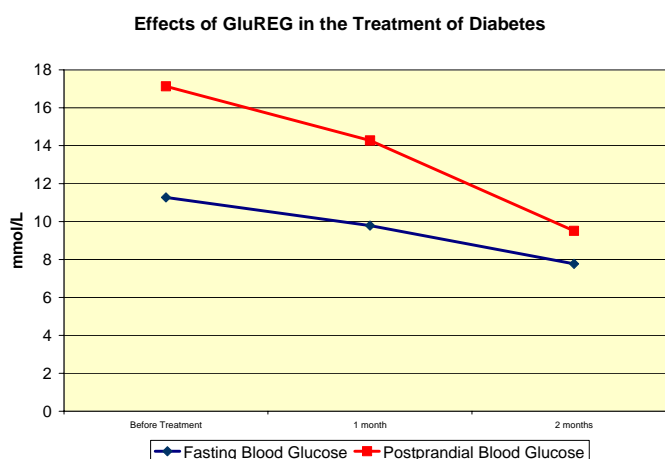
Multi-centered Phase II Double-Blind Controlled Clinical Studies were conducted in 3 major hospitals in Hebei, China. Total 130 diabetes patients participated these studies. The treatment period is 2 months.

The clinical studies demonstrated --

### 2.1 Blood Glucose

	Before Treatment	1 month	2 months
Fasting Blood Glucose (mmol/L)	11.27 +/- 2.18	9.79 +/- 1.65**	7.77 +/- 1.52**
Postprandial Blood Glucose (mmol/L)	17.13 +/- 3.20	14.27 +/- 2.22**	9.51 +/- 2.47**

\*\* p<0.01



### 2.2 Clinical Benefits

Clinical benefits criteria:

(1) Complete Response:

- a. Fasting blood glucose decreases to  $\leq 7.2$  mmol/L, and
- b. 2-hour Postprandial glucose decreases to  $\leq 8.3$  mmol/L, and
- c. 2/3 of the symptoms disappears:
  - Fatigue
  - Frequent urination, excessive thirst
  - Extreme hunger
  - Unusual weight loss
  - Irritability
  - Blurry vision

(2) Partial Responses:

- a. Fasting blood glucose decreases to  $\leq 8.3$  mmol/L, and
- b. 2-hour Postprandial glucose decreases to  $\leq 10.0$  mmol/L, and
- c. At least 1/3 of the symptoms disappears (as above listed).

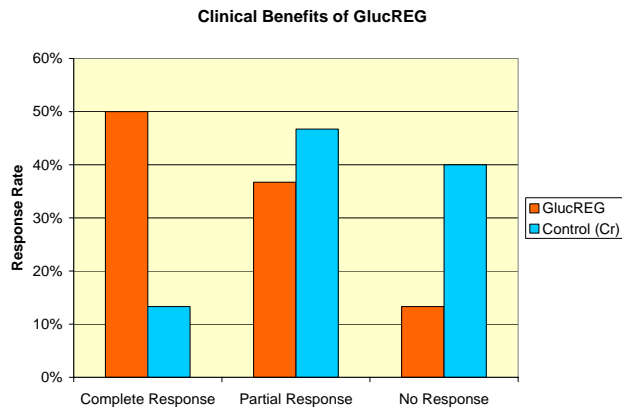
(3) No Response: After 2 months of treatment with GlucREG™, fasting glucose, postprandial

glucose and symptoms did not respond to the treatment.

Results:

	Complete Response	Partial Response	No Response
GlucREG	50.0%	36.7%	13.3%
Control (Chromium Chelates)	20.0%	40.0%	40.0%

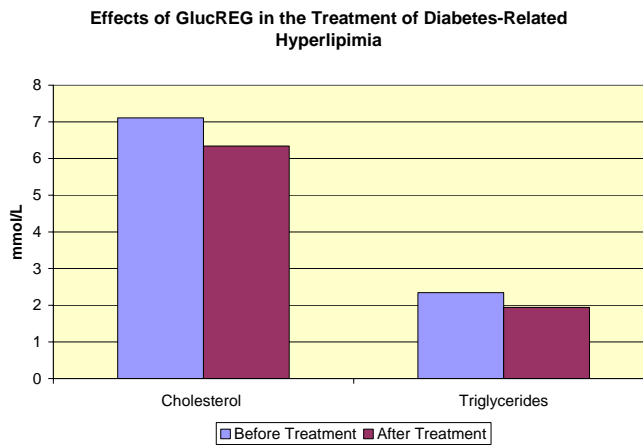
Chi Square test result:  $X^2=5.48$ ,  $p<0.05$



### 2.3 Blood cholesterol

In the study, there are 34 cases complicated with hyperlipimia, the treatment with GlucREG decreases blood cholesterol and triglycerides levels.

	Before Treatment	After Treatment	T	P
Cholesterol (mmol/L)	7.11+/- 1.33	6.34+/-1.00	3.46	<0.01
Triglycerides (mmol/L)	2.34+/-1.07	1.94+/-0.91	4.37	<0.01



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**Summary:**

In vitro studies demonstrated that GlucREG™ sensitizes body's response to insulin by increasing insulin bindings and internalization. As a result of better utilization of insulin, muscle cell glucose uptake is increased.

Clinical studies demonstrated that GlucREG™ reduces blood glucose levels in Type 2 diabetes patients. GlucREG™ brings to Type 2 Diabetes patients significant **clinical benefits**, which is a comprehensive measurement of a variety of clinical parameters including blood glucose and symptoms.

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