

# DIAMYD

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August 28, 2006

OFFICE OF INTERNATIONAL  
CORPORATE FINANCE

## VIA FEDEX

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of International Corporate Finance  
100 F Street N.E., Mail Stop 3628  
Washington, D.C. 20549  
Phone: 202 541 3450



06016477

# SUPPL

Re: Diamyd Medical AB  
File No. 82-34956  
Documents Furnished Pursuant to Rule 12g3-2(b)

Ladies and Gentlemen:

We hereby submit, pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934, as Amended, the enclosed press releases and Stockholm OMX stock exchange presentation of Diamyd Medical AB:

Press release dated as of August 18, 2006 "DIAMYD MEDICAL TO PRESENT AT STOCKHOLMSBORSEN"

Press release dated as of August 21, 2006: "PRESENTATION AT OMX-DIAMYD MEDICAL TO COMMENT PHASE II RESULTS FROM ITS TYPE 1 DIABETES STUDY"

Press Release dated as of August 21, 2006: "DIAMYD™ DIABETES DRUG SHOWS EFFICACY IN A PHASE II TYPE 1-DIABETES TRIAL"

Press Release dated as of August 23, 2006: "PRESENTATION MATERIAL AVAILABLE AT DIAMYDS WEBPAGE"

Presentation dated August 23, 2006: "DIAMYD MEDICAL "Reporting of Phase II Type 1 Diabetes Trial" Presentation at OMX

Kindly acknowledge receipt of the enclosed material by stamping the copy of this letter and returning it in the self-addressed stamped envelope provided.

Very truly yours,

*B* PROCESSED  
SEP 06 2006  
THOMSON  
FINANCIAL

*Michael A Christini*  
Michael A. Christini

*dlw*  
9/5

Enclosure

cc: Erika Hillborg



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**DIAMYD MEDICAL TO PRESENT AT STOCKHOLMSBORSEN** -5 A 10: 22

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Press Release, August 18, 2006

**DIAMYD TO PRESENT PHASE II RESULTS FROM TYPE 1-DIABETES STUDY EARLIER THAN PLANNED (SWEDEN OMXS: DIAM B; USA ADR: DMYDY)**

Diamyd Medical announces that the compilation of data from the Diamyd™ Phase II study in 70 children and adolescents with type 1-diabetes is advancing quicker than provisioned and that results from the study now are planned to be released on Tuesday, August 22nd after closure of the Stock Exchange.

**About Diamyd Medical:**

Diamyd Medical is a Life Science company focused on developing treatments for diabetes and its complications. The Company's furthest developed project is the GAD-based drug Diamyd™ against autoimmune diabetes. Diamyd™ is currently involved in two ongoing clinical Phase II trials of both type 1- and type 2 diabetes patients. GAD65 is a dominating autoantigen in autoimmune diabetes and is the active substance in Diamyd™. GAD65 is also an enzyme that converts the excitatory neurotransmitter glutamate to the inhibitory transmitter GABA. In this context GAD may have an important role not only in diabetes, but also in several CNS-related diseases. Diamyd Medical has an exclusive world-wide license from the UCLA in Los Angeles regarding the therapeutic use of the GAD65 gene. Diamyd Medical has outlicensed the use of the GAD65-gene to Neurologix Inc., New York, for treatment of Parkinson's disease and clinical Phase I studies are ongoing. Other projects comprise drug development within gene therapy using the patent protected NTTDS system (Nerve Targeted Drug Delivery System). The projects mainly make use of Enkephalin and GAD and are targeted for chronic pain e.g. diabetes pain or cancer pain. All projects in this field are in preclinical phases. Diamyd Medical has offices in Stockholm (Sweden) and in Pittsburgh (USA) and its shares are quoted at the Stockholmborsen O-List (OMX:DIAM B). The Diamyd share is also traded in the US through a Level 1 ADR program administered by the Bank of New York. (ticker symbol: DMYDY). Further information is to be found on the Company's website; [www.diamyd.com](http://www.diamyd.com).

For further information, please contact::

Anders Essen-Möller President Tel: +46 (0) 8-661-0026 Cell: +46-70-551-0679 E-mail: [Anders.Essen-Moller@Diamyd.com](mailto:Anders.Essen-Moller@Diamyd.com) Diamyd Medical AB (publ). Linnégatan 89 B, SE-115 23 Stockholm, Sweden. Tel: +46 8 661 00 26, fax: +46 8 661 63 68 or email: [info@diamyd.com](mailto:info@diamyd.com). VATno: SE556530-142001.

This Information may include statements concerning historical, present and forward-looking items and are to the "best of knowledge" of the management of Diamyd Medical and the actual status may differ materially from these statements. The Company assumes no obligation to update these statements to reflect actual results, changes in assumptions or changes in other factors affecting such statements. The Company's Press Releases, Quarterly Reports and Annual Reports ("Information") are translations from Swedish originals. No guarantees are made that these translations are free from errors.



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**PRESENTATION AT OMX - DIAMYD MEDICAL TO COMMENT PHASE II RESULTS  
FROM ITS TYPE 1 DIABETES STUDY**

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**Press Release, Stockholm, Sweden – August 21, 2006 – Diamyd Medical AB  
(SWEDEN OMXS: DIAM B; USA ADR: DMYDY)**

Diamyd Medical announces that it will comment on the results of its phase II clinical trial in type 1 diabetes patients. The press conference will be held at the Stockholm Stock Exchange on Wednesday August 23 at CET 11.00 in the large auditorium. The press conference will also be broadcasted over internet ( <http://www.mamato.se/clients/fine/diamyd/060823/> ).

Speakers at this web-casted event include:

- i) Johnny Ludvigsson, Professor of Pediatrics, Faculty of Health Sciences, Linköping University, and Principal Investigator of the ongoing Diamyd™ Phase IIb clinical trial in 70 children with recent onset Type 1 diabetes;
- ii) Anders Essen-Moller, President and CEO, Diamyd Medical, Stockholm

**About Diamyd Medical**

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Other projects comprise drug development within gene therapy using the patent protected NTTDS system (Nerve Targeted Drug Delivery System). The projects mainly make use of Enkephalin and GAD and are targeted for chronic pain e.g. diabetes pain or cancer pain. All projects in this field are in preclinical phases.

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## Contact Information

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## **DIAMYD™ DIABETES DRUG SHOWS EFFICACY IN A PHASE II TYPE 1-DIABETES TRIAL**

**Press Release, Stockholm, Sweden – August 22, 2006 – Diamyd Medical AB  
(SWEDEN OMXS: DIAM B; USA ADR: DMYDY)**

Diamyd Medical announces that its lead drug candidate, Diamyd™, has demonstrated overall statistically significant efficacy in preserving insulin production in a Phase II clinical trial in 70 children and adolescents with type 1-diabetes. No serious adverse events associated with the therapy were observed. The Principal Investigator found that the treatment is easy to give and that the study outcomes are of clinical importance for the treatment of type 1-diabetes.

The Diamyd™ Phase IIb results will be commented on during a live web-cast (www.diamyd.com) press conference at the Stockholm Stock Exchange on Wednesday, August 23<sup>rd</sup> at 11:00 a.m. Central European Time.

The results from the Diamyd™ study demonstrate that the group of 35 recently diagnosed type 1-diabetes patients that received Diamyd™ produced approximately twice as much meal stimulated insulin (as measured by C-peptide) 15 months after the first treatment as compared to the placebo group ( $p \sim 0.01$ ). Preserving insulin-production is crucial for delaying the complications associated with long-term diabetes which cost billions of dollars to treat.

The ability of the beta cells to produce insulin in response to a meal is considered to be the key factor when it comes to assessing beta cell function. As insulin and C-peptide are produced in equal amounts and C-peptide is easier to measure, meal stimulated C-peptide levels are the most important parameter to follow in a type 1-diabetes study where the aim is to preserve beta cell function. The C-peptide production in both groups experienced a decline but the decline was significantly inhibited in the Diamyd™ group. There were no significant differences in fasting C-peptide levels between the two groups. The treatment itself consisted of two injections of 20 µg Diamyd™, one at day one and one at day 30.

“This is a breakthrough”, states Johnny Ludvigsson, M.D. Professor of Pediatrics at the University Hospital, Linköping University, Sweden and the Principle Investigator of the study that was carried out at 8 hospitals in Sweden. “This clearly offers the potential to improve treatment of type 1-diabetes. Endogenous insulin production is very important as it helps patients to better control their disease and reduce complications. The demonstrated effect is of clinical importance. The treatment is very easy to give, only two injections in total and it was very well received by patients, parents and doctors. In this trial, safety was not an issue.”

“Although preliminary, the results of this trial constitute a major landmark in Diamyd Medical’s history”, says Anders Essen-Möller, CEO of Diamyd Medical. “Our goal is to bring novel therapies to the millions of patients who suffer from diabetes, a growing, worldwide health crisis. It is encouraging that the Diamyd™ drug now has shown statistically significant efficacy in both type 1-diabetes and in the autoimmune form of type 2-diabetes (LADA). The Company will now evaluate and execute its strategies on how to bring Diamyd™ to the market. This may include taking Diamyd™ to the market ourselves, aggressively seeking high-value international pharmaceutical partnerships for the co-development of Diamyd™, or a mixture of both.”

“That Diamyd™ demonstrated the ability to preserve the function of pancreatic beta cells in type 1-diabetes patients is a very encouraging trial result”, states Professor Mark Atkinson, Sebastian Family Eminent Scholar for Diabetes Research at the University of Florida, from which Diamyd Medical has licensed the rights to use GAD65 for treatment of diabetes. “Major studies such as the ‘UK Prospective Diabetes Study’ and ‘the Diabetes Control and Complications Trial’ indicate that maintenance of endogenous insulin secretion is associated with better metabolic control, as well as a lower risk for hypoglycemia and chronic complications. As Diamyd administration preserved metabolic function, this would suggest that significant short and long term benefits might be associated with the use of this drug as a treatment for type 1-diabetes. Those benefits would not only include an improved quality of life for those with type 1-diabetes but in addition, therapies that preserve beta cell function should provide a tremendous cost saving tool as a majority of the expenses associated with the disorder are, in fact, related to the treatment of complications.”

“I’d like to congratulate Diamyd Medical regarding these positive results” says Professor Jerry Palmer, Director at Diabetes Endocrinology Research Center and Professor of Medicine at University of Washington. “With statistically significant better endogenous C-peptide production in the Diamyd™-treated group over placebo the drug seems clearly to be effective. This is an important breakthrough for autoantigen specific therapy. I look forward as the US Lead Investigator to contributing to the success of future clinical studies with the hope that Diamyd may help patients to achieve better control of their diabetes and to experience less long term complications”.

“This is brilliant. These positive results are more striking than any of the other studies reported to date” says David Leslie, Professor of Diabetes and Autoimmunity at the Royal London and St. Bartholomew’s School of Medicine, University of London.

“It’s tremendously satisfying to see our work go from the lab to a clinical application with the potential to help so many people”, says Daniel Kaufman, Ph.D., Professor, UCLA Department of Molecular and Medical Pharmacology, whose research team first developed and tested the vaccine in diabetes-prone mice.

“With these positive results in the type 1-diabetes study the likelihood that our ongoing LADA study will be successful has increased dramatically” says Professor Carl-David Agardh, Malmo University Hospital, Malmo Sweden, Principal Investigator of the on-going 160-patient LADA study. “Type 1-diabetes is known to be a more aggressive disease than LADA so we are optimistic that Diamyd™ will continue to show effectiveness also in this slower-developing form of diabetes”, continues Professor Agardh.

Diamyd Medical’s research program was preceded by studies from the early 1980s where Professors Johnny Ludvigsson, Ake Lemmark, and Steinun Baekkskov discovered the autoantigen that later proved to be GAD65, the active ingredient in the Diamyd™ therapeutic. The GAD genes were subsequently isolated by Dr. Allan Tobin’s laboratory at UCLA. In 1996, Drs. Daniel Kaufman and Jide Tian, (UCLA) demonstrated that GAD-specific autoantigen therapy could effectively prevent type 1-diabetes-prone mice, providing a proof-of principle for subsequent clinical trials.

The study results reported in this press release are preliminary and provisional. Conclusions may be up-dated when detailed analyses become more complete.

A scientific and in depth presentation of the study results will be presented on September 17, by Professor Johnny Ludvigsson at the European Diabetes Congress, EASD, in Copenhagen.

### **About Diamyd Medical**

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GAD65 is a dominating autoantigen in autoimmune diabetes and is the active substance in Diamyd™. GAD65 is also an enzyme that converts the excitatory neurotransmitter glutamate to the inhibitory transmitter GABA. In this context GAD may have an important role not only in diabetes, but also in several CNS-related diseases. Diamyd Medical has an exclusive world-wide license from the UCLA in Los Angeles regarding the therapeutic use of the GAD65 gene. It also has been granted a license from the University of Florida for the use of GAD in therapeutic applications related to the treatment of type 1-diabetes.

Diamyd Medical has outlicensed the use of the GAD65-gene to Neurologix Inc., New York, for treatment of Parkinson's disease and clinical Phase I studies are ongoing.

Other projects comprise drug development within gene therapy using the patent protected NTTDS system (Nerve Targeted Drug Delivery System). The projects mainly make use of Enkephalin and GAD and are targeted for chronic pain e.g. diabetes pain or cancer pain. All projects in this field are in preclinical phases.

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**PRESENTATION MATERIAL AVAILABLE AT DIAMYDS WEBPAGE**

**Press Release, Stockholm, Sweden – August 23, 2006 – Diamyd Medical AB  
(SWEDEN OMXS: DIAM B; USA ADR: DMYDY)**

The presentation material that Diamyd Medical will show today at the press conference at the Stockholm Stock Exchange at 11.00 CET, will also be available on Diamyds webpage.

The material consists of the powerpoint presentation that President Anders Essen-Moller and Principal Investigator Johnny Ludvigsson hold as well as a webcast of the actual press conference.

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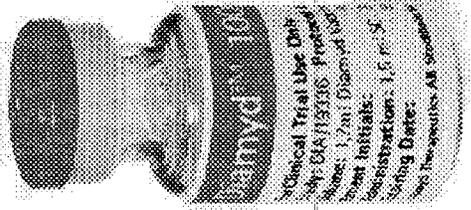
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# DIAMYD MEDICAL

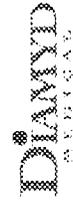
## Reporting of Phase II Type 1 Diabetes Trial

Presentation at OMX  
23 August 2006

Anders Essen-Möller, President & CEO, Diamyd Medical  
Johnny Ludvigsson, MD, PhD, Professor of Pediatrics, Linköping University



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## Principal Investigator on Diamyd™ Type 1 Diabetes Trial

Johnny Ludvigsson, M.D., Ph.D

- ▶ Professor of Pediatrics, Div of Pediatrics and Diabetes Research Centre, Linköping University, Sweden
- ▶ Leading expert in diabetes therapies and active in several immune intervention trials over the past decades GAD(64kD) first found in his patients (Nature 1982)

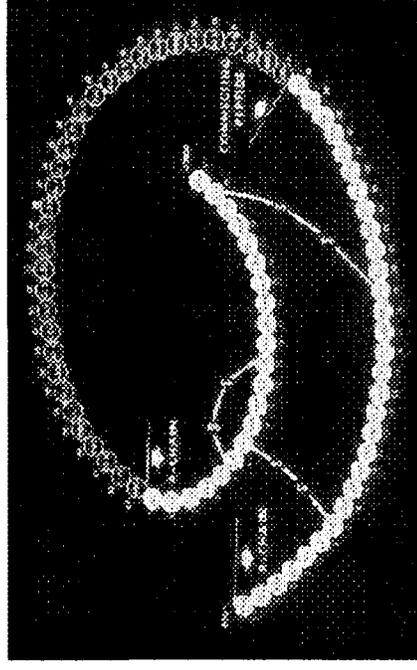
## Overview of Type 1 Diabetes Phase II Trial

- ▶ 70 patient double-blind placebo-controlled trial in 8 clinical centers
- ▶ Statistically significant efficacy as measured by C-peptide levels
- ▶ No drug-related serious adverse events
- ▶ Therapy is easy to administer and is well-accepted by patients and care providers

*Implication: Diamyd™ slows autoimmune diabetes progression.*

# Type 1 Diabetes – Disease with Severe Complications

- ▶ Autoimmune disease
- ▶ Destruction of insulin producing cells
- ▶ Lack of insulin produces diabetes leading to severe complications and early death.
- ▶ Saving beta cells can prevent diabetes, lessen severity of the disease, or even cure the disease.



## Diamyd-GAD Vaccination in Recent Onset Type 1 Diabetes Phase II Started Jan 2005

- ▶ Randomized, double blind, placebo-controlled clinical trial.
- ▶ 70 patients with Type 1 diabetes since 0-18 months.
- ▶ 35 patients in each group received either Diamyd™ 20 microg or placebo subcutaneously at days 1 and 30.

*Ludvigsson et al.*

## Patient Inclusion criteria

- ▶ 10 - 18 years of age at diagnosis of Type 1 diabetes and at first vaccination.
- ▶ Fasting C-peptide 0.1 nmol/l or more at screening.
- ▶ Positive for GAD65 auto antibodies at screening.
- ▶ Written informed consent both from patient and both parents.

## Phase II Study Measurements

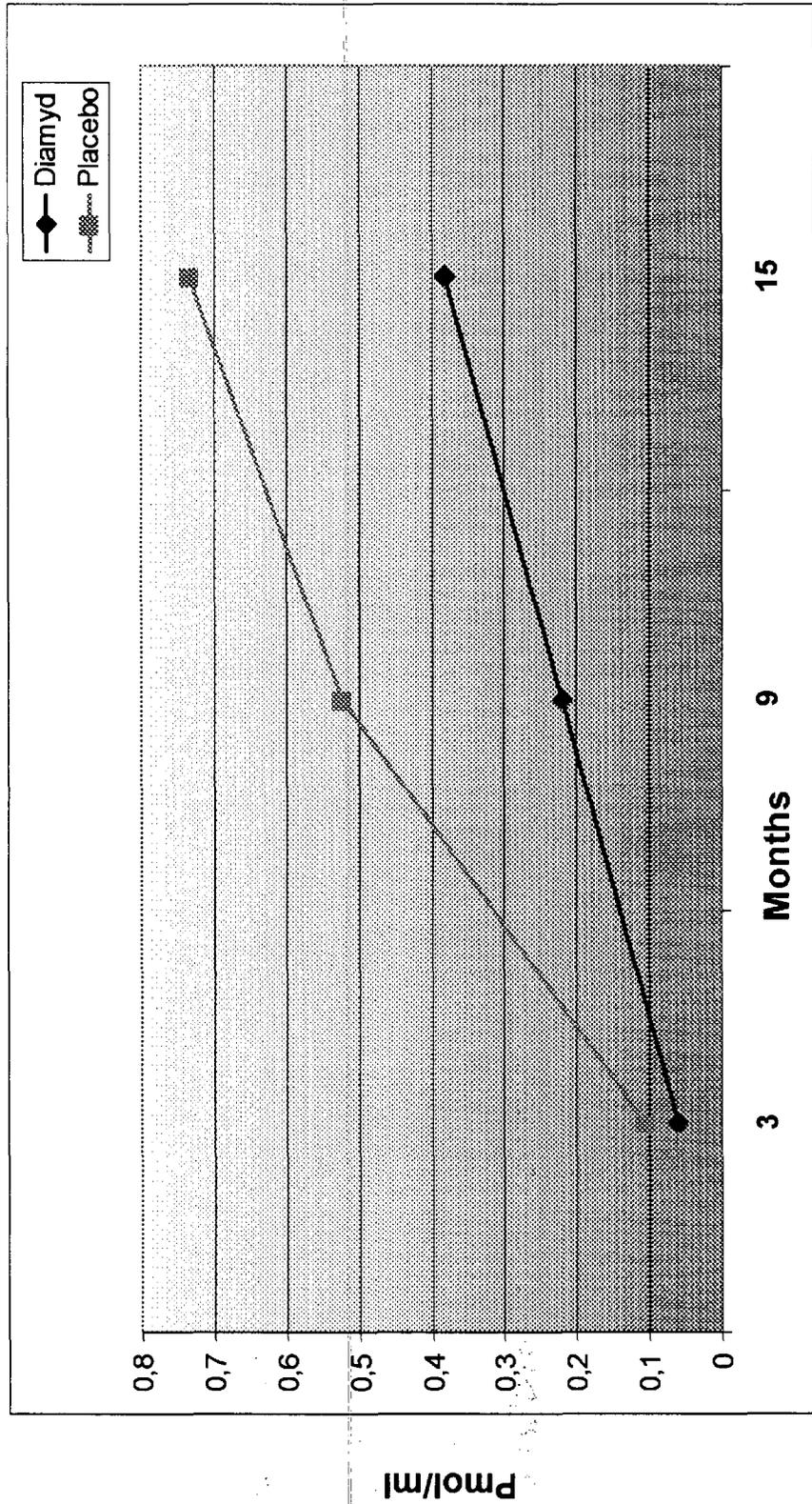
- ▷ C-peptide after Sustacal-load (meal-stimulated)
- ▷ Fasting C-peptide
- ▷ Insulin dose (IU/kg, 24 hrs)
- ▷ HbA1c levels

## Phase II Preliminary Results

- ▶ GAD65 treatment group showed higher C-peptide levels after sustacal load at 9 months than the placebo group ( $p=0.02$ ).
- ▶ GAD65 treatment group showed higher C-peptide levels after sustacal load at 15 months than the placebo group ( $p=0.01$ ).
- ▶ No significant differences in fasting C-peptide levels between the two groups.
- ▶ No serious adverse events associated with drug.

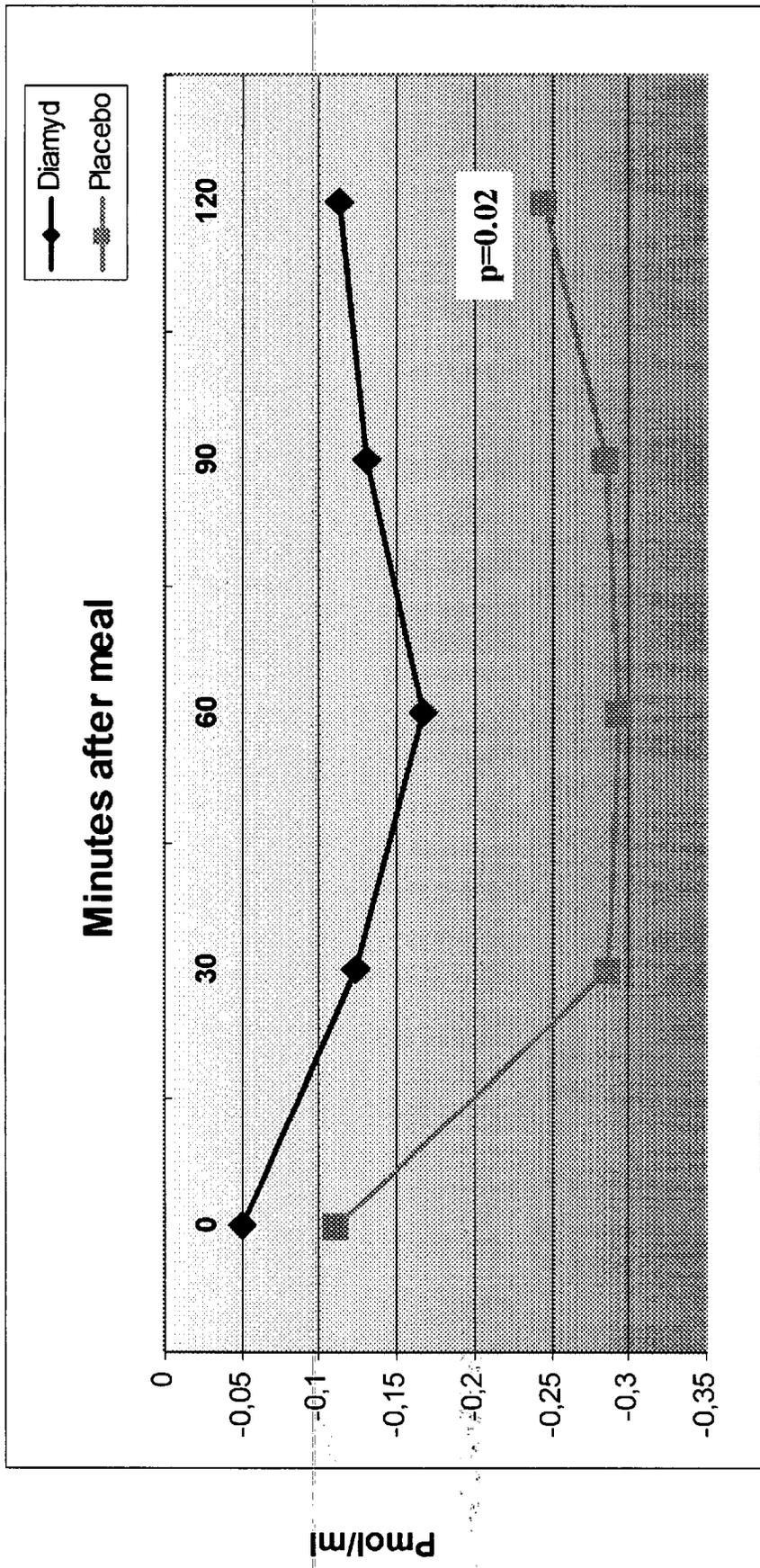
*Ludvigsson et al.*

# Loss of C-peptide by Area Under the Curve

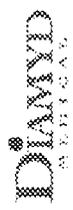


**Conclusion: Decline in C-peptide levels for placebo group was nearly 2 times greater than for Diamyd™ group.**

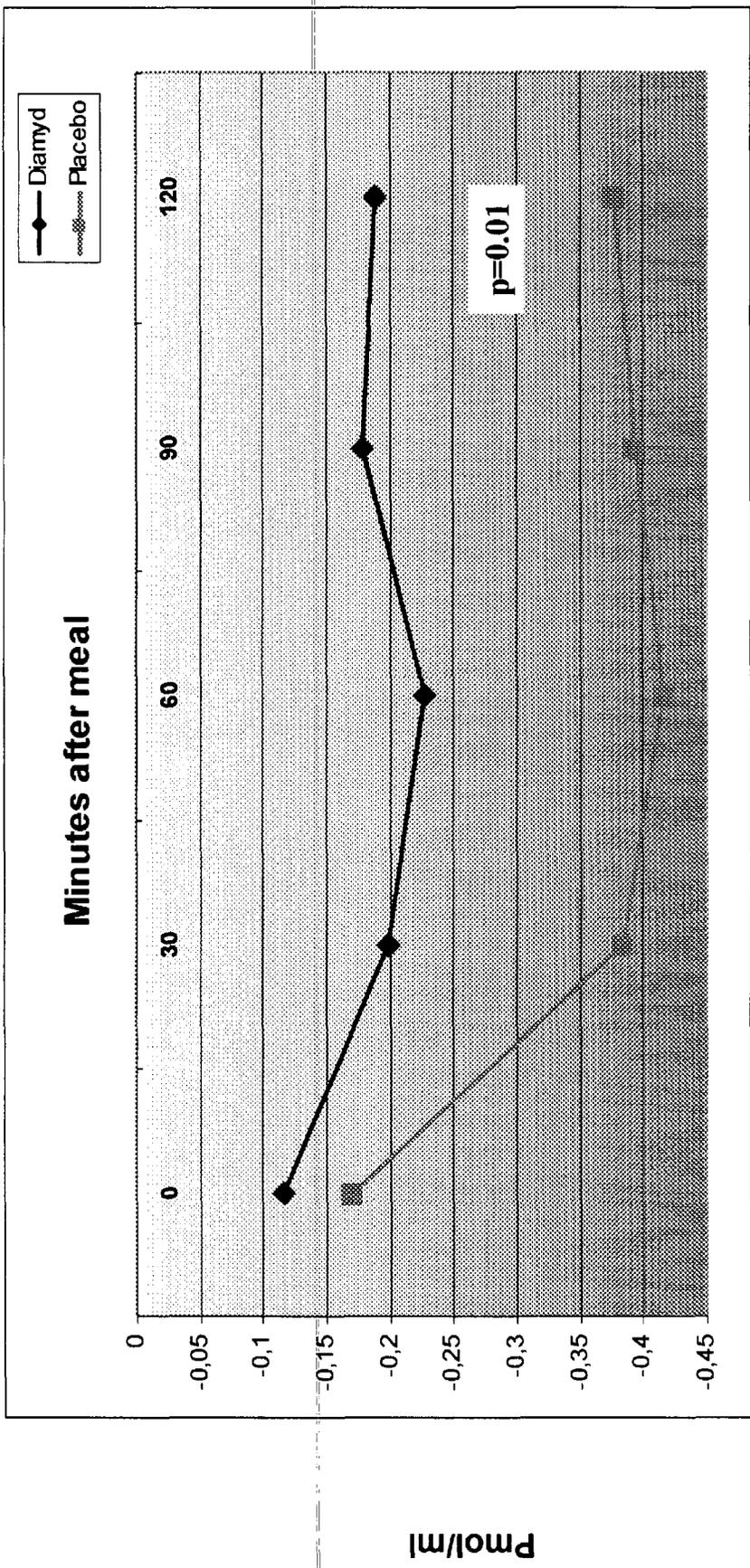
# Change from Day 1 in C-peptide after Sustacal Challenge 9 Months



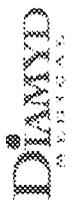
**Conclusion: Over a 2 hour period after a meal, Diamyd™ treatment group's C-peptide production declined less than placebo group when compared to measurements obtained at day 1.**



# Change from Day 1 in C-Peptide after Sustacal Challenge 15 Months



**Conclusion: Over a 2 hour period after a meal, Diamyd™ treatment group's C-Peptide production declined less than placebo group when compared to measurements obtained at day 1.**



## Adverse Events

	Diamyd	Placebo
Connective tissue	3	6
Nervous system	3	3
Immune System	2	1
Blood	1	1
Serious AE	1	3

There were no treatment-related Serious Adverse Events.

## Phase II Summary

- ▷ GAD 65 has demonstrated efficacy in slowing the decline of C-peptide Levels after sustacal load.
- ▷ GAD 65 therapy proposes a novel, first-in-class therapy for slowing the progression of autoimmune Type 1 diabetes.
- ▷ GAD 65 offers a compelling therapeutic option for type 1 diabetes due to ease of use and patient acceptance.

## Diamyd Medical Future – Product Development

- ▶ Initiate plan for major Type 1 studies in US and Europe.

*Jerry Palmer, MD, Univ. of Washington in US will run US trials.*

*Johnny Ludvigsson MD, PhD Linköping University will run European trial.*

- ▶ Phase III product supply from Protein Sciences.
- ▶ Complete ongoing 160 patient Type 2 (LADA) study in June 2007.
- ▶ Likelihood of success for demonstrating efficacy in 2<sup>nd</sup> major diabetes indication is improved.

## Diamyd Medical Future – Product Positioning

- ▷ Develop plan for Diamyd™ product launch

*Opportunity: Type 1 and autoimmune Type 2 (LADA) indications*

*Licensing, co-development, or launch independently*

- ▷ Financing options to support Phase 3 trials

*Potential exercise of warrants by 31 August 2006,*

*Licensing and Partnership fees*

*Equity financing opportunity at high valuation enhanced*

# Question and Answer Session