Biodel Inc. Announces VIAject(TM) Data at Oral Presentation at the American Diabetes Association Meeting


Interim results of Biodel's Phase III clinical trials demonstrated statistically significant daily meal-time (prandial) dose reductions in patients with Type 1 and Type 2 diabetes using VIAject(TM). Type 1 patients receiving VIAject(TM) showed a 28% reduction in daily prandial dose while control patients receiving Humulin(R) R showed a non-significant increase of less than 1%. Type 2 patients receiving VIAject(TM) showed a 49% reduction in daily prandial dose while control patients receiving Humulin(R) R showed a non-significant increase of 2.3%. VIAject(TM) is a very rapid-acting form of injectable human insulin for meal-time use by patients with Type 1 or Type 2 diabetes and is comprised of commercially available recombinant human insulin and our proprietary formulation of ingredients, all of which are Generally Regarded As Safe (GRAS) by the Food and Drug Administration (FDA). Biodel is currently evaluating VIAject(TM) in ongoing Phase III clinical trials.

"We are encouraged that the VIAject(TM) Phase III data continues to meet our expectations and are pleased to share our interim findings in the context of a respected scientific forum provided by the ADA," stated Solomon Steiner, CEO of Biodel. "We plan to advance VIAject(TM) and other product candidates utilizing our proprietary VIAdel(TM) technology and look forward to bringing much needed therapies to the patient population."

Data was also presented from a Phase II study of 16 subjects with Type 1 diabetes. Subjects received either VIAject(TM) or regular human insulin (Humulin(R) R) after a standardized meal and postprandial blood glucose (BG) was monitored. Plasma insulin and blood glucose levels were determined throughout the study. Administration of VIAject(TM) resulted in statistically significantly faster insulin absorption than regular human insulin and lower insulin levels after three hours. The baseline corrected BG profile following the meal was significantly lower during the early time periods of 0-120 and 0-180 minutes, indicative of less hyperglycemia. The mean total glucose infused to maintain normal blood glucose levels was 5 times lower with VIAject(TM) than with regular human insulin, indicative of less hypoglycemia. This data showed that VIAject(TM) provides better postprandial blood glucose control with less hyperglycemia in the first three hours after the meal and less risk of hypoglycemia in the next five hours as compared to regular human insulin.

Biodel noted that its clinical trials are continuing, and that the final results of the trials may be different than those suggested by the interim data presented.

About VIAject(TM)

Our lead clinical candidate is VIAject(TM), a very rapid-acting form of injectable human insulin for meal-time use by patients with Type 1 or Type 2 diabetes. VIAjet(TM) is comprised of commercially available recombinant human insulin and our proprietary formulation of ingredients, all of which are GRAS by the FDA. Our proprietary formulation delivers insulin in a form which closely resembles the way a normal body uses insulin to help glucose enter the body's cells, providing energy that allows the body to function. Current insulin therapies are not delivered quickly enough to simulate the desired meal-time insulin spike. In tests to date, the VIAject(TM) formulation of insulin promotes a more rapid absorption, which more closely mirrors the effects of naturally produced insulin in non-diabetics thereby providing more effective blood glucose control. This novel therapy is currently undergoing two pivotal Phase III clinical studies. The two studies, one involving 400 patients with Type 1 diabetes and the other involving 400 patients with Type 2 diabetes, are comparing the effects of VIAject(TM) to Humulin(R) R, the leading recombinant human insulin.

Biodel believes the potential advantages of VIAject(TM) are:

* VIAject(TM) may provide a safer therapy than the currently marketed meal-time insulin treatments;

* VIAject(TM) more closely mimics the natural spike of first-phase insulin release in non-diabetics, possibly reducing the risk of hyperglycemia;

* VIAject(TM) may allow for a lower dose of insulin required to adequately
cover a meal compared to Humulin(R) R and Humalog(R), the market-leading insulin products;

* VIAject(TM) may reduce the amount of insulin that remains in the bloodstream several hours after a meal, reducing the risk of hypoglycemia; and

* VIAject(TM) may prevent weight gain.

About Biodel Inc.

Biodel Inc. is a development stage specialty biopharmaceutical company located in Danbury, Connecticut. The Company is focused on the development and commercialization of innovative treatments for endocrine disorders, such as diabetes and osteoporosis. Biodel develops product candidates by applying proprietary formulation technologies to existing drugs in order to improve their therapeutic results. The Company has two insulin product candidates currently in clinical trials for the treatment of diabetes. Additionally, the Company has two preclinical product candidates for the treatment of osteoporosis.

Safe Harbor

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company's forward-looking statements are subject to a number of known and unknown risks and uncertainties that could cause actual results, performance or achievements to differ materially from those described or implied in the forward-looking statements, including, but not limited to, our ability to secure FDA approval for our product candidates under Section 505(b)(2) of the Federal Food, Drugs and Cosmetic Act; our ability to market, commercialize and achieve market acceptance for product candidates developed using our VIAdel(TM) technology; the progress or success of our research, development and clinical programs, the initiation and completion of our clinical trials, the timing of the interim analyses and the timing or success of our product candidates, particularly VIAject(TM) and VIAtab(TM); our ability to secure patents for VIAject(TM) and our other product candidates; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; our estimates of future performance; our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of those collaborations after consummation, if consummated; the rate and degree of market acceptance and clinical utility of our products; our commercialization, marketing and manufacturing capabilities and strategy; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; and other factors identified in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007. The Company disclaims any obligation to update any forward-looking statements as a result of events occurring after the date of this press release.

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SOURCE Biodel Inc.

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