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RICHMOND, Va., Jan 8, 2002 (BW HealthWire) -- Insmed Incorporated (Nasdaq: INSM) announced today positive results from a Phase II dose-ranging trial of SomatoKine® in patients with type 2 diabetes. SomatoKine is a recombinant protein drug with insulin-sensitizing activity and is being developed for the treatment of subjects with either type 1 or type 2 diabetes who are unable to maintain adequate blood glucose control with current standard treatments.

"We continue to be impressed with the potent insulin-sensitizing and glucose lowering effects of SomatoKine and the absence of significant side effects," said Geoffrey Allan, Ph.D., president and chief executive officer of Insmed. "The efficacy, safety and pharmacokinetic data obtained from this study combined with the consistent results reported previously establish a clear profile of activity of the product. Most noteworthy is the consistent observation that the effects of SomatoKine can be achieved with a once daily dosing regimen."

This study was placebo controlled and double-blinded with an 8-day treatment duration to determine the efficacy, safety and pharmacokinetics of SomatoKine in subjects with type 2 diabetes. Thirty-seven subjects were randomized to receive either placebo or SomatoKine at dose levels between 0.125-2mg/kg once daily in the evening. All subjects were on insulin therapy prior to enrollment and continued to receive appropriate insulin doses during a 4-day run-in period as well as during the treatment period.

The primary endpoint measurement was the change in average daily insulin requirement as an indirect indication of insulin sensitivity. Improvements in insulin sensitivity and fasting blood glucose occurred with the administration of SomatoKine with the most pronounced changes achieved with a dose of 2mg/kg. At this dose a significant decrease in average daily insulin requirement from 70.8 units at baseline to 56.5 units (-20.2%) at the end of the treatment period was observed. The corresponding insulin dosage change in the placebo group (n=4) was from 89 units at baseline to 87.3 units (-1.9%) at the end of the treatment period.

Other outcome measurements included the change in fasting blood glucose which was decreased from 171.5mg/dl at baseline to 102.2mg/dl on treatment day 8 (-40.4%) in the group receiving 2mg/kg of SomatoKine versus a decrease from 151.5mg/dl to 134.8mg/dl (-11%) for the patient group receiving placebo.

The study further revealed a dose-dependent occurrence of mild hypoglycemia, which suggests that patients on SomatoKine therapy could have further lowered their daily insulin dose to achieve a desirable fasting blood glucose concentration.

In conclusion, the results demonstrate that a single daily dose of SomatoKine can be an effective adjunct to insulin in patients with type 2 diabetes whose blood glucose is poorly controlled by standard insulin regimens.

About Insmed Incorporated

Insmed Incorporated is a biopharmaceutical company focused on the development of drug candidates for the treatment of type 2 diabetes and other metabolic and endocrine disorders associated with insulin resistance. The Company is developing SomatoKine®, a recombinant human protein that is targeted towards the management of both type 1 and type 2 diabetics who are less sensitive to insulin therapy. Previous results from Phase II clinical trials have merited presentations at the annual meeting of the American Diabetes Association, the annual meeting of the Endocrine Society and publication in The Journal of Clinical Endocrinology and Metabolism. These clinical trials demonstrated that SomatoKine significantly decreased daily insulin requirements and lowered fasting blood glucose. In conjunction with SomatoKine, the Company is developing

INS-1, an orally active small molecule that restores insulin sensitivity to tissue. The Company is developing INS-1 for the treatment of type 2 diabetes and polycystic ovary syndrome, a significant women's health disorder. Further information is available at <http://www.businesswire.com> Today's News On The Net - Business Wire's full file on the Internet with Hyperlinks to your home page.
