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RICHMOND, Va.--(BUSINESS WIRE)--June 2, 2003--Insmed Incorporated (Nasdaq:INSM) presented data to ASCO from recent studies of the Company's anti-tumor agent, recombinant human insulin-like growth factor binding protein-3 (rhIGFBP-3), which demonstrated significant decreases in cancerous growth in models of human breast cancer.

The studies conducted in the laboratory of Professor Jeffrey Holly of the Royal Infirmary in the United Kingdom were designed to investigate the actions of rhIGFBP-3 in models of human breast cancer. In malignant cells, the results demonstrated that rhIGFBP-3 enhanced apoptosis induced by ceramide, antimycin A and the UV-mimetic 4 NQO between 50-200%. The study also demonstrated that rhIGFBP-3 enhanced paclitaxel-induced apoptosis by 20-25%. In normal cells, rhIGFBP-3 also enhanced paclitaxel-induced apoptosis. The death of cells by ceramide was reduced by 50% with rhIGFBP-3 administration.

These results confirmed that rhIGFBP-3 potentiated apoptosis induced by a variety of chemotherapeutic agents. Furthermore, the results indicated that with selected agents, rhIGFBP-3 not only enhanced efficiency of cell death induction, but also added specificity accentuating the death of malignant cells while protecting normal cells.

Professor Holly observed, "The ultimate goal for any cancer therapy is to kill cancer cells but not the healthy cells of the patient. Very few current therapies have this advantage and our data suggests that rhIGFBP-3 has great promise in conferring such selectivity. This is not totally surprising as IGFBP-3 is naturally present at high levels in the body without compromising healthy cells but compelling evidence from a number of laboratories indicates that it will enhance the death of cancer cells."

Geoffrey Allan, Ph.D., President and Chief Executive Officer commented, "These results demonstrate the potential of rhIGFBP-3 to not only enhance breast cancer treatment, but also offer a protective effect on normal cells. This could clearly have great benefit for the cancer patient from the untoward side effects of chemotherapies. Our collective data set warrants the pursuit of future human clinical trials, which we expect to initiate in the first half of 2004. We are committed to maximizing the future of this promising drug candidate for the millions of cancer patients who need better, safer treatment options."

The presentation abstract, #3480, is titled, "Enhancement of chemotherapy induced apoptosis of breast cancer cells by recombinant human IGFBP-3: Differential effects on transformed/non-transformed cells according to apoptotic trigger." It will be presented Monday, June 2, from 9:00 a.m.-1:00 p.m. in S Hall A2.

The abstract is available on Insmed corporate website. To access it, go towww.insmed.com, click on "Product Pipeline" and then click on the Cancer development timeline arrow.

For reprints, please contact Baxter Phillips, at 804.565.3041 or bphillips@insmed.com.

Canadian studies show rhIGFBP-3 impact on lung, breast and colon tumors

Two additional abstracts will be presented at the Annual Meeting of the American Association of Cancer Research (AACR) rescheduled for July11-14 at the Washington Convention Center in Washington, D.C.

The studies conducted in the laboratory of Dr. Brian Leyland-Jones of McGill University were designed to examine the anti-tumor effect of rhIGFBP-3 in three solid tumor models: lung, breast and colon, with the objective of determining the potential therapeutic capability of rhIGFBP-3 in human trials. The results of this study, published in the abstract titled, "Insulin-Like Growth Factor-Binding Protein 3: Single Agent and Synergistic Effects with Chemotherapeutic Drugs on Solid Tumour Models", demonstrate the following:

1. rhIGFBP-3 inhibited lung tumor growth by 70% as a single agent in mice.

2. rhIGFBP-3 increased the effect of paclitaxel from 33% to 61% in mice bearing human breast tumors.

3. rhIGFBP-3 inhibited colorectal tumor growth in mice by 25% as a single agent and increased the inhibitory effect of irinotecan from 30% to 69%.

In summary, rhIGFBP-3 exhibited either single agent or combinatorial anti-tumor effects in three solid tumor models. No signs of rhIGFBP-3 toxicity were noted in any of the animal studies.

The study conducted in the laboratory of Dr. Michael Pollak, also of McGill University, was designed to evaluate the effects of rhIGFBP-3 on radiation therapy in breast cancer cells. The results are published in the abstract titled, "Radiosensitizing effect of rhIGFBP-3 on MCF-7 Breast Cancer Cells In Vitro", which demonstrate the following:

1. rhIGFBP-3 alone resulted in a dose-dependent inhibition of cell proliferation, with a maximum suppression of approximately 45%.

2. The data also showed that rhIGFBP-3 enhanced the apoptotic effects of radiation, producing an additive effect on the inhibition of colony formation.

Based on these data, the effect of rhIGFBP-3 on radiation-induced apoptosis in models of human cancer warrants further investigation.

Targeting Cancer

The World Health Organization estimates that by 2020, the number of annual worldwide cancer related deaths is expected to reach 10 million. Although there are several drugs available to treat cancer, the use of most of these drugs produce significant side effects and decrease the quality of life of the patient. The identification of the signaling pathways that regulate tumor growth has led to novel strategies for the treatment of cancer and new agents that target these signaling pathways are emerging as promising new treatments. Herceptin®, approved by the FDA in 1998, is a prime example of this novel class of anti-cancer agents, which hopes to garner a portion of the $21 billion oncology market.

IGFBP-3: A Naturally Occurring Anti-Cancer Agent

Insmed's proprietary product, rhIGFBP-3, is a protein that is normally found in the human bloodstream. It has been shown to induce cancer cell death in a variety of experimental systems. Several studies have demonstrated that cancer risk increases with decreasing levels of circulating IGFBP-3. In addition, recent independent studies have demonstrated that IGFBP-3 can induce cell cycle arrest and enhance the efficacy of chemotherapeutic agents. Insmed is currently engaged in an active preclinical program with leading clinical oncologists and world experts in the field of IGFBP-3 research to evaluate the efficacy of rhIGFBP-3 as a therapeutic agent and to define the optimal clinical protocol with which to translate these promising observations into human clinical trials.

About Insmed

Insmed Incorporated develops pharmaceutical products for the treatment of metabolic and endocrine diseases with unmet medical needs. The Company's most advanced product candidate, the rhIGF-I/rhIGFBP-3 complex is a novel delivery composition of IGF-I that regulates essential metabolic and anabolic (growth promoting) processes, such as glucose uptake and tissue regeneration. Insmed is developing the rhIGF-I/rhIGFBP-3 complex for the treatment of Growth Hormone Insensitivity Syndrome (GHIS) and both type 1 and type 2 diabetes. The Company's second product candidate, rhIGFBP-3, is a recombinant protein that is being developed as an anti-cancer agent targeted towards the inhibition of solid tumor growth. Further information is available at the company's corporate website: www.insmed.com

Statements included within this press release, which are not historical in nature, may constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements regarding expected financial position, results of operations, cash flows, dividends, financing plans, business strategies, operating efficiencies or synergies, budgets, capital and other expenditures, competitive positions, growth opportunities for existing or proposed products or services, plans and objectives of management, demand for new pharmaceutical products, market trends in the pharmaceutical business, inflation and various economic and business trends. Such forward-looking statements are subject to numerous risks and uncertainties, including risks that product candidates may fail in the clinic or may not be successfully marketed, the company may lack financial resources to complete development of product candidates, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission. As a result of these and other risks and uncertainties, actual results may differ materially from those described in this press release.

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