Insert Therapeutics, Inc.

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**FOR IMMEDIATE RELEASE**

# INSERT THERAPEUTICS, INC. REPORTS IN VIVO PERFORMANCE OF DRUG DELIVERY PLATFORM

*Preclinical results demonstrate successful targeted, intracellular drug delivery*

**PASADENA, CA** – February 11, 2003 – **Insert Therapeutics, Inc.** reported that its senior scientist Dr. Suzie Hwang Pun presented data on the company's proprietary Cyclosert™ drug delivery technology at the Non-Viral Systems & *In Vivo* Applications Symposium in San Diego on December 10, 2002. Cyclosert's drug delivery technology offers the unique potential for targeted intracellular systemic delivery of a broad range of therapeutics.

Dr. Pun reported preclinical data demonstrating that Insert's Cyclosert non-viral delivery technology could be modified with ligands to achieve targeted delivery and expression of the p53 tumor suppressor gene in tumor cells. The studies were conducted as part of a research collaboration with San Diego-based Canji, Inc., a subsidiary of Schering-Plough Corporation. Study results indicate that similar levels of the p53 gene were delivered by Cyclosert and by transferrin-modified Cyclosert to tumor cells of tumor-bearing mice following systemic administration. However, expression of the gene, as measured by p53 mRNA, was only detected in tumor cells of those animals treated with transferrin-modified Cyclosert. This suggests that targeting plays a critical role in the intracellular delivery and expression of therapeutic genes administered systemically using non-viral delivery systems. The choice of transferrin as a targeting agent is based on the observation that the transferrin receptor is up-regulated on the surface of many cancer cells.

"Targeted delivery of systemic therapeutics using components that recognize and bind to specific cell or tissue types have the potential to be a significant advance in treating cancer and other diseases throughout the body," said Dr. Pun. "The results of these preclinical studies, together with other studies conducted at Insert, demonstrate that Cyclosert's potential for targeted delivery extends beyond DNA to include delivery of other nucleic acids, including RNA, siRNA, DNAzymes, ribozymes and chimeric oligonucleotides as well as small-molecule drugs."

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Insert's technology platform is based on small cyclic repeating molecules of glucose called cyclodextrins. Insert has developed modified cyclodextrins as building blocks of an entirely new proprietary class of materials, linear cyclodextrin-containing polymers, which Insert calls its "Cyclosert" technology. Animal studies have confirmed that Cyclosert polymers are non-toxic and non-immunogenic, even after repeated administration. In addition to facilitating the targeted delivery of nucleic acids, Cyclosert has also been conjugated to small-molecule anti-cancer agents, resulting in significant improvement in the solubility, stability, toxicity, efficacy and pharmacokinetic characteristics of the compounds.

"We are excited about the positive preliminary results of our work with Canji for the targeted delivery of therapeutic genes to cancer cells *in vivo*," said Leonard Borrmann, Pharm.D., President and Chief Executive Officer of Insert Therapeutics. "Cyclosert has the potential to be an efficient delivery system and to significantly enhance the performance of systemically administered compounds that currently present formulation and delivery challenges."

**CANJI, INC.**

Canji, Inc. is a biotechnology company engaged in the development of innovative therapeutics based on tumor suppressor genes, cell-cycle regulators and growth modulators. The company's initial research efforts are focused on the two best-characterized tumor suppressor genes, p53 and RB, and on identifying efficient, reproducible gene delivery systems. Canji is a wholly owned subsidiary of Schering-Plough Corporation (NYSE: SGP) of Kenilworth, N.J., a research-based pharmaceutical company engaged in the discovery, development, manufacturing and marketing of pharmaceutical products worldwide.

**INSERT THERAPEUTICS, INC.**

Insert Therapeutics, Inc., a privately held biopharmaceutical delivery company, is pioneering the development of targeted, intracellular delivery systems for small molecule drugs and genes. Insert's technologies are designed to facilitate the efficient uptake and release of a broad range of therapeutics directly into cells. The company's proprietary delivery system, Cyclosert™, uses cyclodextrins as building blocks to create an entirely new class of drug delivery materials – linear cyclodextrin-containing polymers. Non-toxic and non-immunogenic at therapeutic doses, Cyclosert is designed for repeat and/or continuous administration, even with nucleic acid drugs. For more information, visit www.insertt.com.

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