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Alain Rolland is Vice President, Research & Development and Head of The Woodlands Center at Valentis, Inc., a publicly traded biologics delivery company formed in March 1999 through the merger of GeneMedicine and Megabios. At Valentis, he leads the company's plasmid therapeutics program to create and develop clinical candidates. Prior to the merger with Megabios, he was first Director of Gene Delivery and then Vice President of Research at GeneMedicine [from] June 1993 to March 1999, where he helped to create the company's infrastructure, its science programs and products. In these different operational roles and also as a project leader, he contributed to creating proprietary gene delivery technologies and products that reached a clinical development stage for the treatment of cancer and cardiovascular diseases, as well as neuromuscular and pulmonary disorders.

From 1989 to 1993, Dr. Rolland was Head, Formulation Research at the R&D Center of Galderma International (CIRD) in France. He led a group of scientists to create and develop novel topical therapeutic systems, mainly for dermal and transdermal applications. He was also responsible for the manufacturing of phase I clinical products. From 1987 to 1988, he was at the Advanced Drug Delivery Research Center of Ciba Geigy Pharmaceuticals in the UK. He developed technologies for drug targeting, focusing on injectable, sterically stabilized nanoparticulate carrier systems for prolonged circulating half-life in blood.

Dr. Rolland received his Pharm.D. in 1981, DEA degree in Pharmacokinetics and Biopharmaceutics in 1983 from Rennes University (France). He obtained his Ph.D. in Pharmaceutical Sciences in 1987 from Rennes University after inventing, characterizing and developing novel polymeric nanoparticles for targeting anticancer drugs to the liver that were evaluated in a phase I/II clinical trial for the treatment of hepatocellular carcinoma. He has published over 60 scientific articles and book chapters, and edited scientific books *(Advanced Gene Delivery: From Concepts to Pharmaceutical Products,* Harwood Academic Publishers, 1999; *Pharmaceutical Particulate Carriers: Therapeutic Applications,* Marcel Dekker, 1993). He is the recipient of numerous awards and he is a member of several scientific societies, including the American Controlled Release Society, the American Association of Pharmaceutical Scientists, and the American Society of Gene Therapy. He is also on the Editorial Board of scientific journals such as the *Journal of Pharmacy and Pharmacology, Advanced Drug Delivery Reviews,* the *Journal of Controlled Release* and *Current Pharmaceutical Biotechnology.* He holds several patents in the field of drug/gene targeting and formulation.

Pharmaceutical Gene Medicines for Local and Systemic Therapy

Somatic gene therapy intends to provide specific cells of a patient with the *genetic software* required to produce therapeutic proteins for the prevention, modulation, or correction of a disease. One of the unique advantages of harnessing the patient's body to produce therapeutic proteins by administration of plasmid therapeutics as pharmaceutical products (i.e., *gene medicines*) is to create a radically improved quality of pharmacological response for the prophylactic and therapeutic treatment of genetic or acquired diseases. The opportunity of administering formulated plasmids, as pre-drugs, that use the patient's body to produce proteins in a natural, controllable, cell-specific manner would introduce a new quality of medical treatment. The success of gene medicines will require the ability to control both the location and the functioning of an administered gene in accessible tissues (e.g., skeletal muscle, solid tumors) in order to provide local or systemic effects (e.g., in cardiovascular diseases with angiogenic and hematological factors, or in cancer treatment with immunotherapy and anti-angiogenesis). Cell-specific control of gene expression and drug-dependent regulation of gene expression (e.g., with a GeneSwitch™) in vivo would also enable unique product opportunities. In addition, the systemic administration of formulated plasmid to target sites would create additional product opportunities, for instance, in the treatment of disseminated tumors and metastases. This presentation describes some of the technologies and product concepts evaluated in animal models, and gene medicines that are being evaluated in clinical trials for local and systemic gene therapy.