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MonoSol Rx and Midatech Ltd Complete Transbuccal Insulin Delivery Study in Primate Diabetes Model

Proof-of-Concept for Oral Insulin Delivery Achieved in Key Species

Efforts Underway for Human Trials in 2011

Warren, New Jersey and Oxford, UK (January 4, 2011) – MonoSol Rx, the developer of PharmFilm® drug delivery technology, and Midatech Group Ltd., a global leader and centre of excellence for the design, development, synthesis and manufacture of nanomedicines, today announced positive results from a pre-clinical study of insulin PharmFilm, the first-ever oral insulin film formulation to transbuccally deliver an active therapeutic dose of insulin in a diet-induced diabetic primate model.

The two companies are developing insulin PharmFilm under a partnership that leverages MonoSol Rx's PharmFilm and Midatech's biocompatible nanoparticles to develop orally bioavailable formulations of peptides and drugs. This partnership includes a joint venture set up to focus on the development and commercialization of products combining the two companies' respective technologies in the diabetes field.

The transbuccal Pharmfilm delivery of insulin in this Rhesus monkey study represents the most advanced proof-of-concept to date for any investigative oral buccal insulin formulation, and confirms previously announced positive results in two porcine studies. Primates in the study were administered insulin PharmFilm transbuccally, or "inside the cheek," with data confirming delivery of an active therapeutic dose of insulin.

A spokesperson for MonoSol Rx said, "Diabetes is reaching near epidemic proportions globally. For the millions of patients worldwide who require insulin treatment, an easy-to-administer, orally dissolving insulin formulation that eliminates the need for injection could address the fear and stigma associated with daily insulin injections and may improve patient compliance. While several attempts have been made to orally deliver a therapeutic dose of insulin, insulin PharmFilm has overcome the higher development hurdle and delivered superior proof-of-concept results. Our transbuccal results in primate and porcine models demonstrate the therapeutic potential of our insulin PharmFilm formulation across different species, and we look forward to moving into man in 2011."

In addition to insulin PharmFilm, MonoSol Rx and Midatech are also evaluating additional peptides, including GLP-1, for oral buccal delivery. Based on positive results from the first GLP-1 porcine study, additional GLP-1 studies are being planned for 2011.

A spokesperson for Midatech Group stated, "The results of insulin PharmFilm in our primate study validate the film delivery of active insulin across the buccal mucosa for the first time. In addition, we have preclinical proof-of-concept that these results can be achieved in a controlled dose precisely tailored to suit individual needs. We anticipate results from our human clinical trials, slated to commence in the second quarter of 2011, to revolutionize treatment methods and insulin delivery for diabetics worldwide."

*PharmFilm is a registered trademark of MonoSol Rx.

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About Diabetes

Diabetes is a disease associated with high levels of blood glucose resulting from defects in insulin production, insulin action, or both. It is the seventh leading cause of death in the United States and can cause serious health complications including heart disease, blindness, kidney failure, and lower-extremity amputations. According to the Centers for Disease Control, nearly 24 million people in the United States are currently living with diabetes. Globally, more than 230 million people are living with the disease and this number is expected to rise to 350 million within 20 years.

About Insulin

Insulin is a hormone that allows blood sugar to move from a person's bloodstream into cells, giving them energy. Type 1 diabetes results from the body's failure to produce insulin. In type 2 diabetes, the body does not produce enough insulin and/or not using the insulin produced adequately. Among adults with diagnosed diabetes – type 1 or type 2 – nearly 30 percent require daily insulin injections to manage their blood sugar.

About Midatech Ltd

Midatech Ltd, UK, is a world leader in the design, synthesis and manufacture of biocompatible nanoparticles. These nanoparticles can be used to create a wide variety of products with novel characteristics, functions and applications for a number of industry segments including life sciences, electronics and fine chemicals.

Founded in 2000, Midatech Ltd is a private company headquartered in Abingdon, Oxford, UK. In 2005, it registered its manufacturing facility – Midatech Biogune S.L. – in Bilbao, Spain, which became fully operational for cGMP standard design and manufacturing of API nanoparticles in March 2007. In 2008, Midatech Ltd further expanded with the opening of PharMida AG in Basel, Switzerland, which is responsible for clinical development of Midatech's products.

Midatech's biocompatible nanoparticles possess a number of unique properties that make them ideal for diagnostic and therapeutic applications. The nanoparticles are water dispersible and can be designed to diffuse freely *in vivo*, or to target specific cells. With a diameter of less than five nm, unbound nanoparticles are freely excreted by the kidneys, and thereby reduce the likelihood of non-specific *in vivo* accumulation. Their small size potentially enables drug delivery via different routes of administration, including parental, transdermal, mucosal, intradermal, transbuccal, sublingual or intranasal/inhalation. Furthermore, their high-degree of stability to enzymatic digestion makes them attractive for oral administration. The nanoparticles can be designed to evade detection by the host immune system by attaching multiple ligands to the nanoparticle surface, thereby allowing multivalent drug or multi-drug delivery on a single particle. Owing to the fact that the nanoparticles self-assemble in a single synthetic step, commercial manufacturing is simple, safe, scaleable and low cost.

Midatech Ltd. has exclusive world-wide IP for the technology covering design, manufacture and application/use of nanoparticles in both diagnostic and therapeutic pharmaceutical areas as well as in other industries. It also has exclusive world-wide rights for technology relating to the synthesis and applications of self-assembling nanoparticles.

For further company information see www.midatechgroup.com

About MonoSol Rx

MonoSol Rx is a specialty pharmaceutical company leveraging its proprietary PharmFilm® technology to deliver drugs in films. PharmFilm® is designed to benefit patients by improving the convenience, efficacy, and compliance of new and currently marketed drugs. The Company's leadership in film drug delivery is supported by strong intellectual property, a portfolio of commercialized prescription and over-the-counter (OTC) drug products, a pipeline of prescription formulations based on PharmFilm® technology, and two recent FDA approvals - Zuplenz®, the first approved prescription oral soluble film for the prevention of chemotherapy-induced, radiotherapy-induced, and postoperative nausea and vomiting, and Suboxone® sublingual film, the first sublingual film product for the treatment of opioid dependence.

MonoSol Rx's commercialization strategy for all PharmFilm® products is to partner with the innovator or other specialty pharma companies that can sell-in and manage product sales and marketing. PharmFilm® is also a tool to help sales and marketing partners differentiate in competitive markets while offering unique advantages over drugs dosed by traditional tablets, capsules and orally disintegrating tablets (ODTs). For existing and future partners, PharmFilm® formulations can also represent revenue-life cycle extensions for products with patent lives that have expired or are approaching expiration. For press releases and other company information visit www.monosolrx.com

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