

For immediate release  
8 December 2010



## **MonoSol Rx and Midatech to Develop Insulin in PharmFilm®; To Establish Joint Venture**

*Positive Pre-Clinical Data Demonstrate Ability to Deliver Therapeutic Insulin Dose via  
Transbuccal Oral Film*

**Warren, New Jersey** and **Oxford, UK** (December 8, 2010) – 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 their intent to form a joint venture that will focus on the development and commercialization of products combining the two companies' respective technologies in the diabetes field. Initially, the joint venture will focus on commercializing buccally delivered insulin with an appropriate partner.

Preclinical testing in multiple species has demonstrated the companies' ability to deliver active insulin across the buccal mucosa and to decrease circulating levels of glucose in all animal models. Additionally, the companies have successfully evaluated the safety of the nanoparticles in tolerability, acute and chronic toxicity studies in multiple species with no evidence of adverse effects. In support of an investigational new drug (IND) submission for human clinical studies, Midatech and MonoSol Rx are concluding additional pre-clinical studies of buccally delivered insulin in diet-induced diabetic primates and expect to announce data by year's end 2010. The companies plan to initiate Phase I clinical trials during the second quarter of 2011.

A. Mark Schobel, president and CEO of MonoSol Rx, stated, "Based on the results of our pre-clinical studies to date, Midatech and MonoSol Rx intend to accelerate the development of Nanoinsulin™ PharmFilm, which we believe has the potential to offer an unprecedented treatment option for diabetes sufferers around the world. The strength of the data generated so far, and the early indications from our primate study, give us confidence that our nanoparticle oral film platform is capable of delivering a therapeutic insulin dose into the systemic circulation and thus look forward to initiating human clinical trials in early 2011. For the future, it's important to acknowledge that the combination of our respective technologies is applicable to other biologics, and we look forward to exploring additional opportunities together."

The mission of the joint venture will be to address the longstanding unmet need of millions of diabetics who are dependent on insulin injections and who lack a convenient, non-invasive delivery option. Nanoinsulin PharmFilm has the potential to offer diabetic patients the first-ever truly-oral alternative to injectable insulin, and to revolutionize the growing multi-billion dollar global diabetes treatment market.

Professor Tom Rademacher, Chairman of the Midatech Group, remarked, "Following preclinical proof-of-concept studies for Nanoinsulin PharmFilm, our collaboration with MonoSol Rx has achieved groundbreaking results in delivering proteins across the buccal mucosa utilizing PharmFilm and our nanoparticle technology. Bioavailability studies in multiple species have

demonstrated repeatedly that Nanoinsulin PharmFilm delivers significantly more bioactive insulin than all previous attempts to deliver insulin across the oral mucosa or the gastrointestinal tract.

“Based on the existing bioavailability data, the companies believe that the Nanoinsulin PharmFilm offers a significant commercial opportunity and are committed to moving the product into the clinic. Forming a joint venture represents an important step forward in our collaboration and in the pursuit of delivering a predictable dose of insulin in a convenient, transbuccal dosage form for millions of diabetics worldwide.”

\* PharmFilm is a registered trademark of MonoSol Rx. Nanoinsulin is a trademark of Midatech Inc.

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#### **About Midatech Group**

Midatech Group 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](http://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](http://www.monosolrx.com)

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