



NextPharma Technologies Announces that its Sterile Product Development Center in Belgium has been Successful in Formulating, Manufacturing and Labeling a Viscous, Lipid Based Formulation for Clinical Trials

Surrey, UK, 28th January 2010 - NextPharma, the leading European provider of product development, contract manufacturing and cold chain and logistics outsourcing services to the pharmaceutical and biotechnology industries, is pleased to announce that its Sterile Product Development Center in Braine-l'Alleud, near Brussels in Belgium is now successfully manufacturing GMP batches of product for Clinical Trials.

Scientists and manufacturing experts working at NextPharma's new Sterile Product Development Center have formulated, manufactured and labelled one of the first GMP clinical batches for a Phase I/II trial for a controlled-release, viscous, anhydrous and lipid based formulation; the product was successfully shipped to investigational sites and the clinical trial is now under way.

Sean Marett, Managing Director, NextPharma Technologies, Product Development Services commented: "The ability to formulate and manufacture this challenging product was through a combination of the sterile product development team's significant experience in lyophilization techniques combined with utilization of cutting-edge technologies afforded by our new Sterile Product Development Center; this is a very pleasing result". Bill Wedlake, CEO NextPharma commented: "We are aware of the commercial pressure that our customers are under to trial products and make timely decisions regarding moving towards full scale manufacture and we were pleased to be able to demonstrate our skill, flexibility and speed in delivering this important clinical material".

The Sterile Product Development Center is a state of the art facility geared towards the needs of companies around the world requiring high-quality development-scale sterile clinical trials manufacture including full lyophilization capabilities. The new facility is designed to provide customers with a more efficient and faster option to

develop and manufacture their products for clinical trials.

The Sterile Product Development Center supports customers' pharma development projects from pre-formulation and formulation development through to clinical development and manufacturing with lyophilization for Phase I to Phase III clinical trials with scale-up capability to commercial scale in our Braine l' Alleud commercial manufacturing facility, in accordance with the highest regulatory requirements. The Sterile Product Development Center is staffed by scientists and experts in manufacturing and lyophilization cycle optimization who have over forty years collective experience in steriles manufacturing and lyophilization development.

The Sterile Product Development Center has segregated clinical trials manufacturing suites allowing development of high potent products Occupational Exposure Limits (OEL) 4 as well as conventional and biologics injectables including solutions (water and solvent based), emulsions and lyophilized formulations. The Sterile Product Development Center has the capability to provide products filled into glass and plastic vials and pre-filled syringes.

All clinical materials are manufactured and supplied in accordance with cGMP requirements of US FDA, EMEA and other regulatory agencies.

The facility's analytical laboratories provide a full range of biological and small molecules drug testing, analytical development, lyophilization cycle development and validation services. Stability programs are conducted according to International Conference on Harmonization (ICH) guidelines.

The facility has been designed to a high level of containment, which together with stringent training and strict waste management procedures, allows the safe handling of highly potent compounds to OEL 30ng/m³. A risk assessment of all new products entering the Sterile Product Development Center is performed prior to the start of pharmaceutical formulation development and clinical trials manufacturing.

We have strong expertise in cytotoxic production with the ability to manufacture

batch sizes for early phase clinical programmes of a few hundred rising to 110,000 vials of product for a Phase III clinical programme.

NextPharma develops, manufactures, packages, and distributes a broad range of products and formulations for its customers including solids, liquids and semi-solid dosage forms, antibiotics, hormones and controlled release medicines. It has an established leadership position in the high technology area of injectables manufacturing (lyophilized and liquid fill), with particular expertise in product development and manufacture of oncology medicines.

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Contact:

Bill Wedlake

Chief Executive Officer

NextPharma Technologies Holding Limited

Tel +44 (0) 1483 479 121

www.nextpharma.com

Notes to Editors:

About NextPharma

NextPharma Technologies, headquartered in the UK and founded in 2000, is a world class outsourcing partner to the pharmaceutical and biotechnology industry.

We offer a full range of services from early phase product development, through clinical trial packaging (Phases I through III) to high volume commercial manufacturing. We are a world leader in lyophilization, sterile fill finish and pellet technologies and in specialist product manufacturing including cytotoxics, hormones, penicillins, cephalosporins and controlled drugs. Our sterile development and production offers a full range of drug delivery technologies including pre-filled syringes, vials and ampoules. Additionally we have significant expertise in paediatric drug formulation, development and manufacture. NextPharma offers 'one-stop' logistics solutions tailored to meet the needs of the global pharmaceutical industry under the rigid standards of cGSP/GDP regulations.

We operate globally with seven product development centres, seven manufacturing plants and six temperature controlled storage and distribution sites across Europe and North America, supplying customers in North America, Europe and Japan.

We have 1,200 employees dedicated to serving over 200 customers world wide and a customer base, which includes many of the world's leading pharmaceutical, specialty pharma and biotech companies.

We have a proven track record in almost all pharmaceutical technologies and product forms and in addition to the specialist areas above have capabilities in solids, semi-solids, liquids, sprays and dry dosage form technologies.

All of our sites are either FDA inspected, in the process of upgrade for inspection or targeted for upgrade for inspection.