

VII Annual Conference on Platform Technologies March 2015



MIDATECH PHARMA ESPAÑA S.L.U. Part of Midatech Pharma (UK)

H2020 - NANOFACTURING

Midatech Group

Founded in 2004 - Headquarters in Oxford UK

- Word leader in the design, synthesis and manufacture of biocompatible nanoparticles
- Microspheres Polymer compositions for programmable sustained release of actives
- Total Headcount 60 (45 Doctors, PhD's and Scientists)
- Midatech Pharma España
 - Nanoparticle design and Manufacturing Established in the Basque Region in 2006
- Midatech Pharma Wales Microsphere design and manufacture



Midatech Pharma España S.L.U.

- Initially 800 m² expanding to 1,200 m² in 2015
- Licenced by the AEMPS in 2011 for the manufacture of non-sterile nanoparticles under GMP conditions
- First clinical production in 2011
- Complete refit in 2014 for sterile manufacture
- Seeking inspection and licence by end Q2 2015





Possibly the smallest programable nanoparticles in biomedical use

- The design, development and synthesis of the glyconanoparticles is based on a one-step auto-assembly technology
- They are 2 to 5 nm nanoparticles that permit targeting of combinations of therapeutic entities to tissue and /or specific cells





METABOLIC diseases: Novel therapy for Diabetes

- A new method for transbuccal delivery of insulin. Also applicable to other biomedical active peptides
- Phase I clinical trial completed successfully. Phase II programmed for Q2/Q3 2015



ONCOLOGY

• Two principal objectives:

Combined Therapy

Oncology treatment requires a combination of treatments, Mostly through combinations of different anticancer drugs

Targeted treatment

- It is essential that treatment is specifically targeted
- Chemotherapeutics should only kill the cancer cells and not damage healthy ones.





HORIZON 2020 - NANOFACTURING

THE DEVELOPMENT OF MEDIUM AND LARGE SCALE SUSTAINABLE MANUFACTURING PROCESS PLATFORMS FOR CLINICALLY COMPLIANT SOLID CORE NANOPHARMACEUTICALS

Participant No	Participant organisation name	Country	Participant short name
1 (Coordinator)	Midatech Biogune S.L.	Spain	Midatech
2	Centre for Process Innovation Limited	UK	СРІ
3	GalChimia S.A.	Spain	GalChimia
4	ProChimia Surfaces Sp. z o.o.	Poland	ProChimia
5	Applus Services, S.A.	Spain	Applus
6	Midatech Limited	UK	Midatech UK
7	Centre For BioNano Interactions, National University of Ireland, Dublin	Ireland	CBNI
8	Istituto Firc Di Oncologia Molecolare	Italy	IFOM
9	Ecole Polytechnique Fédérale de Lausanne	Switzerland	EPFL



OBJECTIVES

• Scientific Objectives:

- Further develop our existing GMP manufacturing line to supply nanomedicines at Industrial scale.
- Develop a new manufacturing platform process which is cost effective, safe, efficient, robust and regulatory compliant.
- Establish a full spectrum of robust and practical chemical and biological characterization tests and procedures to meet stringent regulatory requirements
- Establish an open access pilot line in Europe for the process development and scale up of nanopharmaceutical manufacture

Additional Objectives:

- Bring an innovative healthcare solution closer to market for millions of sufferers of diabetes
- To create a European manufacturing ecosystem for nanopharma

Work Packages

THE DEVELOPMENT OF MEDIUM AND LARGE SCALE SUSTAINABLE MANUFACTURING PROCESS PLATFORMS FOR CLINICALLY COMPLIANT SOLID CORE NANOPHARMACEUTICALS

- WP1 Project Management and Reporting
- WP2 Platform Assessment and Specification of Technology Platform Requirements
- WP3 Scale-Up of Ligand Manufacture
- WP4 Scale up of existing Reactor-based NP manufacture
 - Non Sterile to Phase III Clinical Scale
 - Sterile add Phase III Clinical scale
 - Add in-house Fill and Finish capability on site
- WP5 Process development and scale up of solid core NP and peptide linked NP manufacture to clinical supply scale
- WP6 Physicochemical and biocompatibility characterization of NPs
- WP7 Evaluation and generation of Concept Designs, guided by preparation of a User Requirement Brief
 - Design for a full scale manufacturing plant
 - WP8 Exploitation and Dissemination

Current basis of Manufacture



- Standard Chemical Reactor
 - Computer controlled
 - Parameters:
 - pH
 - Temp
 - Stirrer Rate
 - Reagent Addition
- Tasks
 - Currently run at 50 ml to 2.000 ml.
 - Will be stepped up to 5.000 and 10.000 ml to feed up to Phase III Clinical Supply
 - 2 Pivotal Studies of 2,000 Patients

Projected Industrial Scale Up

GNP Industrial manufacture using Continuous Flow Technology



GNPI Purification by Continuous Flow Centrifugation

GNP Industrial Purification using Tangential Flow Filtration



These techniques are standard biotechnology applications







"Proyecto financiado el Ministerio de Economía y Competitividad, a través de la convocatoria EQUIPA 2014, de acuerdo a lo previsto en el artículo 31 Reglamento de la Ley 38/2003, de 17 de noviembre, General de Subvenciones, aprobado por Real Decreto 887/2006, de 21 de julio"







Thank you for your attention

Justin N W Barry BSc. Hons. MBiol CBiol QP Eu. Managing Director Midatech Pharma España