PRESS RELEASE

TA101 GOCLIN European funded project for the development of an innovative product for the treatment of rheumatoid arthritis – 1,7M€ total budget

23rd of December 2013 – Lisbon, Portugal

A leading consortium of industrial partners has been awarded a grant by the Seventh Framework Program of the European Union for an innovative research and development project "*TA101 GOCLIN: Clinical development of TA-101 for the treatment of rheumatoid arthritis*" (#606352). The aim of this Project is to take TA101, a small domain antibody developed by TechnoPhage, into the clinical stage of development for rheumatoid arthritis (RA) and develop a novel mode of administration for the market of biologic therapeutics. The project is forecasted for completion in 2015, with a total duration of 26 months. The total budget is EUR 1,72 million corresponding to a total European funding of EUR 1,36 million.

The number of people aged 65 and over in Europe will almost double over the next 50 years, from 85 million in 2008 to 151 million in 2060. RA, being a significant aging-related disease, is considered one of the most crippling types of arthritis, with high costs for patients and society. Moreover, RA has still unmet medical needs for effective and reasonably priced treatments.

TA101 GOCLIN is designed to provide safety data in humans through a clinical trial Phase Ia and Ib and, at the same time, to develop a novel mode of administration of the active compound TA101 allowing the autonomous administration of the drug.

The project aims to undertake (1) the generation of an efficient method for the production of TA101 for clinical studies, (2) the performance of clinical studies Phase I (safety studies in healthy volunteers) and finally (3) the development of an innovative delivery system based on microneedle technology for the efficient and simplified mode of administration of TA101.

T*A101 GOCLIN has mobilized the critical mass of seven industrial partners from 5 European countries. These partners are from Belgium, France, Germany, The Netherlands and Portugal.*

Amspar B.V will design and develop an integrated microneedle patch combination loaded with TA_101. In this regard, Amspar will closely work together with **Laboratoires Plasto Santé** (expert in pharmaceutical patch development) and **MicroCreate BV** (microneedle array manufacturing).
Q-Biologicals NV together with **ARTES Biotechnology GmbH** will develop a suitable microbial expression host and manufacturing process. cGMP material for clinical trials will be produced by Q-Biologicals.
Clinical trials will be conducted by **SGS Life Science Services**.

The consortium is coordinated by **TechnoPhage, S.A., Portugal**. Miguel Garcia, CEO TechnoPhage, comments "*The project combines the novel TA101 compound with an innovative formulation and administration strategy and preliminary data suggest that this approach will provide a significantly greater advantage to patients. It will also allow to obtain considerable European expertise. I am delighted that TechnoPhage is coordinating this program with such a strong team of industrial experts".*

Official project website:
http://ta101goclin.wordpress.com

European Commission online information on the project:
http://cordis.europa.eu/projects/rcn/110463_en.html

About TechnoPhage

TechnoPhage, SA (www.technophage.pt) is a multiplatform biotech company involved in the R&D of new molecules in diverse therapeutic areas. It was founded in 2005 by several researchers and Portuguese companies from the healthcare and pharmaceutical industries. TechnoPhage is a Drug Discovery and Development company run in three business units:
1) Bacteriophage-based products for the treatment of bacterial infections;
2) The Technology of Antibody Fragments (small domain antibodies);
3) Drug discovery using the zebrafish as an in vivo model system.

The company has several patent applications, partnerships with several small and mid-sized pharmaceutical companies and 11 programs in its R&D pipeline including inflammation, infection and neurodegenerative disorders. It develops therapeutics up to CTA/IND and expects to partner with pharmaceutical companies in subsequent stages of development.

TechnoPhage has successfully partnered with several small and mid-sized pharmaceutical companies. One of the most recent collaborative protocol was between TECHNOPHAGE and UCB. TechnoPhage and UCB signed a collaborative protocol to jointly develop new therapeutic agents using TechnoPhage's small-domain antibody proprietary technology. In addition, TechnoPhage has partnered with The Shanghai Institute of Materia Medica (SIMM) to jointly proceed in both pre-clinical and future clinical studies of TA_101 to generate data to support regulatory filings for approval to market TA_101 in the People's Republic of China.

Besides partnering with pharmaceutical companies, TechnoPhage has secured additional funding from the EU (Structural Funds, Eurostar program) for projects with academic partners across Europe. For more information, please contact:

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About Q-Biologicals

Q-Biologicals is offering services to third parties to help them in speeding up the development and manufacturing of their biological products.
The principal technological expertise of Q-Biologicals is the production of recombinant proteins derived from microbial as well as eukaryotic systems, purification of recombinant proteins for research purposes and with pharmaceutical grade quality, including formulation development and stress stability studies. Q-Biologicals also has an extensive expertise in the manufacturing of viruses and living cells for vaccine purposes and in-depth knowledge of working under industrial and cGMP quality requirements. It offers cGMP manufacturing to third parties in a state-to-the art facility.

Q-Biologicals is a private company financed by VIB, the Flemish investment company PMV and LSRP.

This and further news is available at: www.q-biologicals.com

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About ARTES Biotechnology GmbH

ARTES is a Germany-based biotechnology company that specializes in recombinant protein production, process development from microbial expression systems and technology transfer.
ARTES offers generation of optimized production cell lines in proprietary yeast expression systems based on *Hansenula polymorpha* and vaccine development on virus like particle technology (VLP). The company operates worldwide from its 850m2 S1 facilities in Langenfeld, focusing on contract R&D for red and white biotechnology products.
In addition to genetic engineering, ARTES provides fermentation and downstream process development, analytical assay development and production cell line characterization.

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About Amspar

Amspar is an Amsterdam (Netherlands) based privately held company focusing on business development and particularly licensing activities in the pharma- and life sciences sector. Amspar works together with various reputed licensors of pharmaceutical products. Till date Amspar has established close to 20 licensing agreements for generic pharmaceutical products world-wide. Amspar obtained a license related to technology for ceramic nano-porous microneedles arrays from MyLife Technologies BV (Enschede, The Netherlands). More information is available at www.amspar.nl.

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About SGS Life Science Services

SGS Life Science Services is a leading contract service organization providing clinical research, analytical development, biologics characterization, biosafety, and quality control testing. Delivering solutions for bio-pharmaceutical companies, SGS provides clinical trial management (Phase I to IV) services encompassing clinical project management and monitoring, data management, biostatistics, PK/PD Modeling & simulation and regulatory consultancy. SGS' clinical unit located in Antwerp, Belgium with a total of 92 hospitalization beds has successfully passed several US FDA inspections during recent years. For optimized early phase clinical trials, SGS features Sample tracking for safety lab data interfaced with Oracle for PK samples, Full eSource clinic automation (EDC), GMP pharmacy for on-site formulation and a Biosafety Level 2 quarantine facility.

SGS has a wealth of expertise in: First-In-Human studies, QT/QTc prolongation, radio-labeled 14C ADME & PET scan trials, viral challenge testing, biosimilars and complex PK/PD studies. For a qualitative and faster patient recruitment across Americas and Europe, clients can also count on SGS' large data base of investigators and key opinion leaders with an high therapeutic expertise in Infectious Disease & HIV/HCV, Vaccines, Oncology and Respiratory. Clients benefit also from the favorable regulatory environment in Belgium with very short phase I trial approval.

SGS also offers GMP/GLP contract laboratory services that include analytical chemistry, microbiology, stability studies, bioanalysis, virology and protein analysis.

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