



Press Release AF004002

Archivel's RUTI[®], a novel therapeutic vaccine to Latent Tuberculosis, starts phase II clinical trials in South Africa

- **The double-blind, randomized, placebo-controlled phase II clinical trial is designed to investigate the safety, tolerability and immunogenicity of the antituberculosis vaccine RUTI[®] in subjects with latent tuberculosis infection**
- **Archivel will provide vaccine RUTI[®] from its recently certified GMP manufacturing plant in Badalona, Catalonia, Spain**
- **The therapeutic vaccine has potential to significantly reduce the time required for the current antibiotic treatments, one of the unmet needs identified in the fight against tuberculosis worldwide**

BIO Convention, Chicago, II – 5 May 2010. Archivel Farma, a biotechnological company focused on the discovery and development of new immunomodulating biopharmaceutical agents to prevent and treat tuberculosis and other diseases, announced today that the Medicinal Control Council of the Republic of South Africa approved on April 22nd the start of the first clinical trial of the therapeutic vaccine RUTI[®] in latent tuberculosis infection (LTBI).

The trial will be run in 3 centers and will enrol 96 individuals with or without concomitant HIV infection. The primary goal is to evaluate the safety, tolerability and immunogenicity of the vaccine RUTI[®] -- Archivel's proprietary therapeutic vaccine made with detoxified cellular fragments from *Mycobacterium tuberculosis*, the causal agent of tuberculosis. Primary results are expected by year's end.

The therapeutic vaccine has already been tested in a double blind, randomized, placebo-controlled Phase I Clinical trial with 24 healthy volunteers performed in a single site in Catalonia, Spain. The results, published in the January 22nd 2010 issue of the peer-reviewed journal *Vaccine*, demonstrated that the vaccine RUTI[®] is safe, well tolerated and immunogenic, and helped defining the appropriate dosing and regime to be explored in the current phase II trial.

Archivel will manufacture and deliver the vaccine RUTI[®] from its own manufacturing facilities, located in Badalona, close to Barcelona in Catalonia, Spain. The plant obtained the Spanish GMP certification in March 2010. It has a built-in P3 lab that enables the culture and processing of the tuberculosis bacillus (and other pathogenic agents) in order to produce the final sterile, lyophilized preparation that does not require any adjuvants.

Further information can be found in the accompanying press release AF004001 entitled "*Major breakthrough in fight to eliminate Tuberculosis*".

Further information on Archivel at www.archivelfarma.com

Archivel Farma S.L., 61 c/ Fogars de Tordera, Polígon Industrial Bonavista, 08916 BADALONA, Spain. Tel +34 93 497 2456 / +34 637 057432 ORue@archivelfarma.com



Press information and illustrations

Nigel Robson, Vortex PR, Island House, Forest Road, Forest, Guernsey GY8 0AB, UK. Tel +44 (0) 1481 233080 nigel@vortexpr.com

RUTI is a registered trademark of Archivel Farma S.L. all other trademarks are the property of their respective owners.