



PRESS RELEASE

Archivel Farma and Laboratorios Silanes to collaborate in the development of the anti-tuberculosis vaccine RUTI® in México

- RUTI® is the most promising therapeutic vaccine among the dozen projects that are currently being developed in the world.
- Laboratorios Silanes brings to the agreement their extensive knowledge of the regulatory environment and the Mexican pharmaceutical market.

Barcelona/Mexico DF, March 20, 2018. Archivel Farma, owner of RUTI®, the most promising therapeutic vaccine targeting tuberculosis, among the dozen RUTI-related projects that are currently being developed around the world, and **Laboratorios Silanes**, one of the major Mexican pharmaceutical companies, have signed a collaboration agreement for the clinical development and commercialisation of the vaccine in Mexico.

Under that agreement, Archivel Farma will continue managing the Clinical Development Plan for RUTI® providing Silanes with access to the essential confidential information as well as the Scientific Advisory Committee. Silanes, in turn, will advise Archivel Farma with regard to the regulatory affairs and the recommended clinical development of the vaccine in Mexico and will also evaluate the commercial potential of RUTI® in the Mexican market. The agreement grants Laboratorios Silanes a preferential position in obtaining the licence and distribution rights (L&DA) for RUTI® in Mexico.

RUTI® was designed as a therapeutic vaccine for the treatment (not prevention) of different forms of tuberculosis (TB), meant mainly as a solution to treat **Multidrug-Resistant Tuberculosis (MDR-TB)** and as adjuvant for the standard antibiotic treatment to avoid the frequent relapses associated with TB.

The RUTI® vaccine, originally designed by **Dr. Pere-Joan Cardona**, Head of the Experimental Tuberculosis Unit at Institut Germans Trias i Pujol (IGTP) in Badalona (Spain) and the founder and scientific advisor at Archivel Farma, is based on cell wall nanofragments of *Mycobacterium tuberculosis*, the bacillus causing the disease. RUTI® triggers a polyantigenic response that enhances the immune response of the patient, which contributes to combating *Mycobacterium tuberculosis* and promotes its elimination.

TB-causing bacteria can remain latent in the body for decades. It is estimated that each year 90 million people are infected and approximately 10% of them develop tuberculosis. According to WHO, in **2016 10.4 million new TB cases** were diagnosed and there were nearly 1.7 million associated deaths (374.000 of which were people with HIV/AIDS).

In recent years the number of people suffering from TB resistant forms to the first-line of antibiotics (Isoniazida and Rifampicin) has considerably increased. The WHO calculate that there are 490.000 people with MDR-TB and 100.000 with Rifampicin-resistant tuberculosis worldwide. These patients need to be treated with the second-line of antibiotics (aminoglycosides, Ethionamide, Ethambutol and Ofloxacin) which have many more side effects and show only 60% of efficacy, which results in **250.000 annual deaths caused by MDR-TB**. Even though the WHO has recommended new protocols including



a shorter medication administration time, in many countries a 21 months' treatment is still applied, which, in turn, generates high rates of treatment dropout with the corresponding rise in the antibiotic resistances and the associated deaths.

According to WHO, **22.200 new cases of tuberculosis were reported in Mexico in 2016** and more than **2900 people died** from this infectious disease (770 of them, affected by HIV/AIDS). About 2.6 per cent of new cases of TB in Mexico are resistant to the first-line of antibiotics (MDR/RR-TB), which corresponds to 600 cases per year.

Thanks to its strong ability to stimulate the immune response, demonstrated in preclinical and clinical studies, a dose of the RUTI® vaccine combined with antibiotics can reduce the treatment time of MDR-TB and contribute to reducing both the number of deaths and the rate of relapse. For this reason, Archivel Farma have focused their efforts on the development of RUTI® in this context and **has initiated phase IIa** clinical trials to evaluate the safety and immunogenicity of the vaccine. Furthermore, a study has already started in the Netherlands and it is expected soon to extend to Romania. Archivel plan to start to evaluate the efficacy of the vaccine for the treatment of MDR-TB in early 2020.

The agreement between Archivel Farma and Laboratorios Silanes has been managed by trifermedCBDO (www.trifermed.com), the first Contract Business Development Organization with a direct presence in Europe and America.

About Laboratorios Silanes

Laboratorios Silanes is a Mexican company with an international presence, with 75 years of experience in the pharmaceutical sector. Laboratorios Silanes has operations in the US, Central America, the Caribbean, Brazil, most of Latin America, as well as Europe, Africa and the Middle East. Their products are manufactured with the highest quality standards. They develop medicines for diabetes - their main specialty- cardiovascular diseases, acute and chronic pain. Laboratorios Silanes own more than 160 patents thanks to their strong commitment to innovation, a key factor that has led to the creation of new divisions of diagnosis and biological antidotes to treat poisonous stings and/or bites from venomous animals. www.silanes.com.mx

About ArchivelFarma

Archivel Farma was founded in 2005 as a spin-off of Archivel Technologies and is based in Badalona, Spain. Archivel Farma has specialized in the discovery and development of new biopharmaceutical agents to prevent and treat tuberculosis and other diseases susceptible to immunological interventions. Developing their products up to advanced clinical phases, Archivel Farma aims to work with partners to bring their products to the market, thus enabling a great number of people to benefit from them. www.archivelfarma.com

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