



Press Release AF004001

## **Major breakthrough in fight to eliminate Tuberculosis May cut treatment time from nine months to one Phase II clinical trials announced at BIO 2010**

**BIO Convention, Chicago, II – 5 May 2010.** Archivel Farma, S.L. has announced that its breakthrough treatment for tuberculosis (TB) will shortly start phase II clinical trials. The treatment uses the company's unique combination of its novel therapeutic vaccine called RUTI<sup>®</sup> in conjunction with an antibiotic. It has the potential to cut treatment time from nine months to one month, which reduces side effects and healthcare costs, by preventing re-infection during the eradication process.

### **TB is a major global killer**

One third of the world population (2.5 billion) is infected with *Mycobacterium tuberculosis*, the bacteria that cause TB in humans. Every year 100 million people become infected with TB. TB is the second cause of death by infectious diseases after AIDS claiming a life every 12 seconds – 2.5 million deaths each year. Infected people can show no symptoms – Latent TB Infection (LTBI) - but 5-25% will develop active TB at some stage of their life. People with compromised immune systems are particularly vulnerable such as HIV patients who have up to 10% risk per year of developing active TB.

### **Current prevention – only one vaccine at present**

The BCG (Bacillus Calmette-Guérin) vaccination has been in use for 80 years but is only effective at providing infants with protection against developing disseminated tuberculosis for the first ten years of their lives. It has little or no effect in protecting adults, or against pulmonary tuberculosis, the most common form of the disease.

### **Current treatment -- not very effective**

A LTBI is very hard to treat. It requires a nine month course of antibiotics which is often not completed because the patient decides that, as they have no symptoms, they can stop. Not completing the course means that the bacteria has not been eliminated and can re-establish. The powerful antibiotics can also have side effects, such as liver damage, if not closely monitored. A long course is also logistically challenging especially in third world countries where TB is endemic.

### **The problem with treating TB**

It has now been discovered that TB does not lie "dormant" but is actually waging a constant war with the host, constantly re-infecting the lungs. Provided that the host is healthy, it has the upper hand and usually keeps the TB in check – LTBI. *Mycobacterium tuberculosis* is particularly tricky to eliminate as it can be either replicating, when it can be killed by the antibiotics, or non-replicating when the antibiotics are not active against it. The long, nine month course of antibiotics is needed to ensure that all traces of the non-replicating form are eliminated from the lungs. Further details can be found at [http://www.archivelfarma.com/hipotesi\\_an.html](http://www.archivelfarma.com/hipotesi_an.html)

### **Reluctance to treat LTBI**

Health systems in countries where TB is prevalent are reluctant to treat LTBI with a nine month course of antibiotics because patients can easily become re-infected even if they complete the course properly as it provides no immunity. Plus there are the costs and logistics of administering a nine month course. As a result, there remains a reservoir of TB in the population. What is needed is an effective, inexpensive way to treat LTBI to reduce the reservoir.

### **Archivel's novel two pronged approach**

This combines a one month course of antibiotic to eliminate the bacteria in the replicating stage and two injections of the company's RUTI vaccine that stimulates the body's own immune system to fight the bacteria. This combination approach reduces the treatment time from nine months to one, is easier to



manage, less expensive, more effective and more likely to be done completely. The company estimates that cost comparison between the current and new treatment, when allowing for all the logistical costs means that the new treatment costs around half that of the old treatment.

“We believe that we are the only company to have a solution targeted specifically at people who have LTBI,” explained Luis Ruiz, Archivel’s CEO “Several vaccines are being developed by other companies but these tend to focus on either acting as a booster for people who have had the BCG vaccination or who have not LTBI. As our solution is quick, easy to administer and inexpensive, it could be the major step forward required to eliminate TB from the world’s population by directly tackling the reservoir of TB in people with LTBI. Migratory flows and Intercontinental jet travel is ensuring that TB continues to infect people the world over.”

### **The vaccine RUTI®**

RUTI® is a new polyantigenic vaccine for the treatment of Latent Tuberculosis Infection (LTBI). It is a therapeutic vaccine, i.e. it stimulates an immediate immune response by the body to kill the TB, but future trials will be required to see if it conveys any lasting protection from further infections. It is produced from *Mycobacterium tuberculosis*, the strain that actually produces TB, that is fragmented into tiny particles so there are no live bacteria and detoxified in order to eliminate the toxic substances produced by the bacteria. The vaccine RUTI® vaccine is the result of the partnership between the Badalona-based Institut d’Investigació en Ciències de la Salut Germans Trias i Pujol and Archivel Farma. It has been under development since the first patent in 2003 with an investment of more than ten million euros.

### **Phase I clinical trials successfully completed**

The trial in health volunteers, who did not have LTBI, resulted in adaptive immunity production indicating that the desired vaccination effect was achieved without any significant side effects.

### **Phase II clinical trial to start shortly in South Africa**

These trials will determine the safety and immunogenicity of the anti-tuberculosis vaccine and antibiotic combination for patients with LTBI. The company expects that this would be followed by commercial availability in 2015, once its effectiveness will be proven in a following Phase III trial. Full details can be found in the accompanying press release AF004002 entitled “*Archivel’s RUTI, a novel therapeutic vaccine to Latent Tuberculosis, starts phase II clinical trials in South Africa*”.

### **Initial market for the RUTI vaccine**

Archivel believes that the first patients who will benefit from the vaccine RUTI® and antibiotic combination are patients affected by LTBI with compromised immune systems such as those with HIV or patients who require anti-TNF-alpha therapies for, say, rheumatoid arthritis. In the latter case, it is mandatory for them to have the nine month course to treat LTBI first so a reduction to just one month with Archivel’s solution is ideal.

### **Further information on Archivel at [www.archivelfarma.com](http://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](mailto: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](mailto:nigel@vortexpr.com)

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