PRESS RELEASE

ELSALYS BIOTECH concludes with THEA a license option agreement on its ELB011 program in ophthalmology

- **ELB011, a first-in-class antibody program, demonstrates an anti-angiogenic effect on the formation of new blood vessels which cause certain retinal diseases including AMD (age-related macular degeneration)**
- **THEA laboratories, a company specialized in ophthalmology, takes an exclusive license option for the development and commercialization of ELB011.**

Lyon, FRANCE, 22 February 2018, ELSALYS BIOTECH, a new player in French immuno-oncology, has signed a license option agreement with THEA for the development of its ELB011 program in ophthalmology.

The option concerns the clinical development (expected from 2020) and the commercialization of ELB011, a new first-in-class antibody in the treatment of wet AMD and other retinal vascular pathologies. The innovative mechanism of action of ELB011 makes it possible to consider its development in monotherapy or in combination with anti-VEGF agents, the current standard of care for these pathologies, whose efficacy can diminish in the long term.

Jean-Frédéric CHIBRET, Chairman of Théa Laboratories said: «*With this program, THEA aims to enlarge its ophthalmology development portfolio in retinal vascular pathologies. The license agreement calls for an upfront payment on signature, milestone payments and royalties on sales. The exercise of the option could take place by end 2018.*

In our partnership, ELSALYS BIOTECH, specialized in biotechnology, will remain in charge of the initial steps of preclinical development and in particular the production of batches for toxicology studies and clinical trials. THEA will be responsible for full clinical development and commercialization in ophthalmology.»

Jacques MIZRAHI, VP Research & Development ELSALYS BIOTECH said: «*The proof of concept obtained in animal model demonstrates the efficacy of our antibody on a new first-in-class target in ophthalmology and thereby recognizes its therapeutic potential. The drug candidate ELB011 now opens up new therapeutic perspectives for patients with retinal vascular disorders, at least 30% of whom, it is important to remember, do not respond to standard treatment with anti-VEGF. Furthermore, this new approach is fully compatible, in principle, in combination with standard therapies.*»

Christine GUILLEN, CEO ELSALYS BIOTECH, added: «*We have therefore decided to work with THEA for its ability to develop and commercialize ELB011 rapidly. This agreement presents exciting revenue opportunities which will contribute to the financing of our further programs.*»

ELSALYS BIOTECH is advised by Willy Mathot Attorney within the framework of this transaction.

About retinal vascular pathologies

The retinal pathologies expected for the ELB011 antibody are mainly wet age-related macular degeneration (wAMD), proliferative diabetic retinopathy (PDR) and diabetic macular edema (DME), widespread and growing diseases, due in particular to the ageing population and the progression of the epidemic of diabetes.

- Leading cause of blindness among older people, age-related macular degeneration (AMD) can be found in two forms: atrophic or "dry" AMD and exudative or "wet" AMD. Less frequent (10 to 15% of all cases, that is up to 7.5 million patients estimated in 2023[1]) but the most dreaded, the wet form can lead to loss of central vision in a few months or, more likely, a few years.
- Diabetic retinopathy is the most common pathology among individuals with diabetes (around 1/3 of people with diabetes). This complication, characterized by retinal damage driven by micro-vascular changes due to diabetes, can lead to blindness. DME affects almost 12% of diabetics and more specifically patients with diabetes Type 1 (insulin-dependent), where more than one out of three patients are affected.
- Macular edema is the build-up of fluid in the macula that causes it to thicken. The most frequent cause of macular edema is diabetic retinopathy, even if the retinal pathologies that may cause macular edema are numerous, such as, for example, vein occlusion or the post-operative period following cataract surgery. The number of patients with diabetic macular edema is expected to reach nearly 33 million in 2030[2], up more than 50% in 20 years.

By consolidating market projections of the different pathologies targeted by ELB011 (AMD, diabetic retinopathy and macular edema), high growth is expected, to reach $18.4 billion in 2030 followed by a slowdown with the arrival of generic medicinal products on the market.

The common characteristic of these diseases is the development of new blood vessels at the level of the macula (center of the retina). The main treatment of these pathologies consists of intraocular injections of anti-angiogenic drugs – anti-VEGF. If they can halt the progression of the disease in three cases out of four, anti-VEGF improve the patient's vision in only one third of cases. Their efficacy is often only temporary and patients can become resistant to treatment that involves furthermore painful and frequent injections.

[1] Datamonitor
[2] Association for Research in Vision and Ophthalmology - 2011

About ELB011 – anti-CD160 antibody in ophthalmology

ELB011 is an antibody with an innovative mechanism of action with a potentially synergistic anti-VEGF effect.

Preliminary research has opened the possibility of exploring a new route for therapeutic purposes to block angiogenesis in pathological conditions, whilst sparing mature vessels and thereby reducing potential toxic effects of a treatment.

The proof of concept of this strategy was confirmed in a recent study on another pre-clinical model which demonstrated that the injection of ELB011 diminishes the number of lesions and speeds up tissue healing.

About ELSALYS BIOTECH

ELSALYS BIOTECH is a clinical stage immuno-oncology company that designs and develops a new generation of antibodies that target tumors and their immune microenvironment. By modulating the action of immune cells (immunomodulator antibodies) or by blocking the mechanisms that promote tumor growth (targeted antibodies), ELSALYS BIOTECH offers new options to patients for whom therapy is no longer an option.

To convert these targets into drug candidates, the Company uses a world-class academic network, a team and an R&D platform that encompasses sourcing targets to clinical development and the commercialization of antibodies derived from these targets. Today ELSALYS BIOTECH is conducting 5 proprietary development programs including LEUKOTAC® (inolimomab), an immunotherapy antibody that has demonstrated its clinical superiority in Phase 3 in an orphan disease with very poor prognostic: steroid-resistant refractory acute graft-versus-host disease.

Founded in 2013, ELSALYS BIOTECH is located in the heart of the European cluster LYON BIOPOLE. Its founding shareholders are TRANSGENE and SOFIMAC INNOVATION, joined in 2015 by the INSTITUT MERIEUX EUROPE and CREDIT AGRICOLE CREATION.

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About THEA

Today, THEA is the third eye care group in Europe (not including the retina market). Based in Clermont-Ferrand, the laboratory has continued to expand by opening nearly 30 subsidiaries in Europe, North Africa, North and South America, and also the Middle East. Currently, the THEA group constitutes a network uniting more than 1 000 members of staff worldwide, with its products available in nearly 70 countries. THEA is an independent family group, developed

from a Research and Development start-up by Henri Chibret, a fourth generation member of an ophthalmic dynasty. Jean-Frédéric Chibret (a fifth generation family member) has presided over the company since 2008.
The group already proposes a wide range of preventive and curative products for anterior segment ocular conditions, and with the expansion of its R & D activities into the retina field, THEA aims to consolidate its position amongst the leaders of the European ophthalmic market.

Contacts

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