PRESS RELEASE

LEUKOTAC® at the 44th congress of the European Society for Blood and Marrow Transplantation (EBMT)

- **A poster summarising the safety profile results of the randomised Phase 3 testing LEUKOTAC® in patients with steroid-resistant acute graft-versus-host disease (SR-aGvHD) to be presented at the EBMT 2018**
- **ELSALYS BIOTECH to organise a dedicated workshop on LEUKOTAC® with French transplant physicians to discuss the next steps towards making the treatment available again**

Lyon, FRANCE, 15 March 2018, ELSALYS BIOTECH, a new player in immuno-oncology, will present at the 44th EBMT congress which will take place in Lisbon, Portugal, from 18 to 21 March, the progress made on LEUKOTAC® (inolimomab), its monoclonal antibody that recently demonstrated promising clinical results in the treatment of SR-aGvHD.

The company will present a poster on additional analysis of safety data of the Phase 3 study testing LEUKOTAC® vs ATG [a] (control arm) in 100 patients with SR-aGvHD. The data demonstrate that LEUKOTAC® represents a relevant alternative treatment, notably because of its significantly more favourable safety profile as compared to ATG. There are 3 times fewer related adverse events (AE) for all stages with LEUKOTAC® (14%) than with ATG (41%), p=0.004, as well as 2.5 times less related AE of grade 3 or higher (LEUKOTAC® 12% vs ATG 29%, p = 0.04). It is shown as well a clear decrease in potentialy life-threatening infectious episodes such as sepsis and septic shock (14% vs 24% and 4% vs 16% for the LEUKOTAC® and ATG groups, respectively). Other major data concern the increase in overall survival at one year (+ 37%) with LEUKOTAC®, at the limit of statistical significance (HR=0.628, p=0,055 unilateral).

Based on these results, the ELSALYS BIOTECH team will organise, on the sidelines of the EBMT congress, a workshop with French transplant physicians to discuss these results, as well as retrospective data on the administration of LEUKOTAC® collected from more than 120 children in the context of the nominative TUA [b]. The company will present its clinical development plan in this pediatric population and more broadly the next steps towards making treatment available again.

«To date, the French clinicians know LEUKOTAC® best as they have administered it to more than 2,000 patients in compassionate use or in clinical trials. So, logically, we share first and foremost with them about our product's latest data and the next steps we plan in order to better assess how LEUKOTAC® could be integrated into the current management of aGvHD when the product is available,» says **Dr. David LIENS, Medical Director, ELSALYS BIOTECH.**

«The 44th EBMT congress is an important step for ELSALYS since it is the first European medical congress where we present additional analysis of Phase 3 data on LEUKOTAC®. We are moving towards ensuring that this product is made available to the community of transplant physicians and patients at the earliest opportunity,» concludes **Dr. Christine GUILLEN, CEO and Co-founder, ELSALYS BIOTECH.**

[a] ATG: anti-thymocyte globulin.
b Temporary Use Authorisation.

About LEUKOTAC®

LEUKOTAC® (inolimomab) is an immunotherapy monoclonal antibody that targets the interleukin-2 receptor (IL-2), a chemical molecule named cytokine that contributes to the development and proliferation of some white blood cells including T-cells responsible for aGvHD. By linking specifically to the α chain of the receptor (CD25), LEUKOTAC® prevents IL-2 from binding on the surface of the donor's over-active T-cells which blocks their multiplication.

The efficacy of LEUKOTAC® in steroid-resistant aGvHD lies mainly in its specificity and its preferential affinity to the CD25 receptor found on the surface of T-lymphocytes.

About steroid-resistant aGvHD

Formerly called bone marrow transplant, Hematopoietic Stem Cell Transplantation (HSCT) is the last therapeutic option for patients with certain blood cancers or severe immunodeficiency. In practice, the treatment is designed to replace the diseased blood cells of the patient with the hematopoietic stem cells of a matching donor (allograft).

Once grafted, these stem cells will produce new healthy and functional blood cells, including white blood cells that will allow patients to bridge their immune deficiency or to eliminate surviving cancer cells.

If this technique has made considerable progress in 60 years, half of transplant recipients are still victims of complications: side effects of conditioning pretreatment (that aims to prevent transplant rejection), long-term susceptibility to infections and GvHD. In the latter case, the donor's over-active T-cells «turn against» the patient's tissues: mucous membranes, skin, gastro-intestinal tract, liver and lungs. The acute form appears just after the transplant, the chronic form occurring several months later (preceded or not by an aGvHD).

Affecting between 30 to 55% of patients, GvHD is the main complication of transplantation. To halt this "autoimmune disease", physicians combine corticosteroids with other immunosuppressive agents. The fact remains that some 30 to 50% of aGvHD gradually become resistant to these first-line treatments. To date clinicians do not have any standard of treatment for these patients for whom there is a strong unmet medical need. Thus in Europe, 4,000 children and adults die each year from their aGvHD.

About ELSALYS BIOTECH

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

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

www.elsalysbiotech.com

Stay in touch with ElsaLys Biotech and receive directly our press releases by filling our contact form on www.elsalysbiotech.com
And follow us on Twitter: @elsalys_biotech

Contacts

ELSALYS BIOTECH
Dr. Christine GUILLEN
CEO and Co-founder
+33(0)4 37 28 73 00
guillen@elsalysbiotech.com

Presse
ATCG-PARTNERS
Marie PUVIEUX (France)
+33 (0)6 10 54 36 72
Céline VOISIN (UK/US)
+33 (0)6 62 12 53 39
presse@atcg-partners.com