LEUKOTAC ® (inolimomab) is available again in France, following the granting of cohort ATU for the treatment of graft-versus-host disease, corticosteroid-resistant or corticosteroid-dependent, with grade II-IV

- **The French National Agency for the Medicines and Health Products Safety (ANSM) granted a Temporary Authorisation for Use (ATU) so-called cohort ATU (cATU) for LEUKOTAC® (inolimomab) on December 24, 2019.**

- **Inolimomab is therefore available to hematologists or to physicians treating blood disorders and to hospital pharmacists for the treatment of acute cortico-resistant or corticosteroid-dependent graft-versus-host disease after allogeneic hematopoietic stem cell transplantation in adults and pediatric patients over 28 days of age. The indication should be discussed during a multidisciplinary consultation meeting.**

Lyon, FRANCE, January 9, 2020, **ElsaLys Biotech** announced today that the cATU has been granted by the ANSM and its clinical experts, after evaluation of a dossier containing data on the quality, safety and efficacy of the drug based on its administration in several hundred patients included in clinical trials or treated via named patient Temporary Authorization for Use ("ATU nominative") until November 2015. This authorization includes the implementation of a reinforced monitoring (defined in the Protocol for Therapeutic Use) of the efficacy and safety data obtained in patients treated within the framework of this cATU. Inolimomab treatment can only be considered if the patient cannot be included in an ongoing clinical trial.

"We have data that support the benefit of inolimomab treatment in patients with acute corticosteroid-resistant or corticosteroid-dependent graft-versus-host disease (Grades II-IV in Glucksberg classification)," **said Dr. David LIENS, Chief Medical Officer, ElsaLys Biotech**. "*We are delighted with this decision by the ANSM, which allows us to, once again, make inolimomab (1 mg/mL, solution for infusion) available to hematologists in the therapeutic emergency which is this pathology*".

"While we continue to work on the filing of marketing authorization applications (MAA) in Europe and in the US, this ATU demonstrates the therapeutic value of inolimomab in the management of acute graft-versus-host disease (aGvHD). The ATU program in France allows patients, whose survival is at stake, to have access to a therapeutic solution before marketing in Europe, in close collaboration with the competent authority, the ANSM. The implementation of this cATU is effective immediately" **said Dr. Christine GUILLEN, CEO and co-founder of ElsaLys Biotech.**

Considering the potential emergency situation of the indication, it is recommended that hematology specialists anticipate the administrative procedures by contacting the ATU Cell (*by Tel: 0800 08 90 81 - Fax: 01 56 59 05 60 or by e-mail: atu-leukotac@pharma-blue.com*) which is at their disposal for any further information or request for a Protocol for Therapeutic Use and collection of information.

About inolimomab (LEUKOTAC®)

Inolimomab (LEUKOTAC®) 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), inolimomab prevents IL-2 from binding on the surface of the donor's over-active T-cells which blocks their multiplication.

The efficacy of inolimomab in 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 or dependant to these first-line treatments. To date clinicians do not have any standard of treatment approved in Europe 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 which designs and develops a new generation of therapeutic antibodies targeting tumors and their immune and/or vascular microenvironment.

To convert these novel targets into drug candidates, the Company is currently conducting 5 proprietary development programs including inolimomab (LEUKOTAC®), an immunotherapy antibody that has recently demonstrated its clinical superiority in Phase 3 and that is closed to market approval in an orphan "post-cancer" 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 shareholders are TRANSGENE, SOFIMAC INNOVATION, joined in 2015 by IM EUROPE, a subsidiary of INSTITUT MERIEUX, and CREDIT AGRICOLE CREATION, and in 2018 by LABORATOIRES THEA.

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