

## Long-term survival analysis of the randomised Phase III study shows a clear clinical benefit of inolimomab in SR-aGvHD

- Follow-up of INO-107 Phase III study patients up to 8.5 years is the first long term analysis of a randomized study in acute steroid-resistant graft versus host disease (SR-aGvHD)
- Investigators letter published in Blood Advances journal completes the result of the initial analysis of INO-107 study and demonstrates clinical benefit of inolimomab in SR-aGvHD
- This analysis shows a clear superiority of inolimomab against anti-thymocyte globulin

Lyon, FRANCE, 23 January 2019, ELSALYS BIOTECH, a new player in immuno-oncology, presents the results from long-term follow-up of INO-107 Phase III study patients up to 8.5 years. These results have been published in a [Letter to Blood](#) signed by the investigators demonstrating clinical benefit of inolimomab (LEUKOTAC®) in acute steroid-resistant graft versus host disease (SR-aGvHD).

This randomized multicentre controlled parallel-group Phase 3 study (France/ Belgium) included 100 adult patients with grade II-IV SR-aGvHD treated with inolimomab versus control ATG (anti-thymocyte globulin – approved in this indication in France only) between 2009 and 2015. In this study, patients were enrolled in 15 centres and followed for one year.

For all the patients still alive at the end of the study (23 [47%] and 20 [40%] patients in the inolimomab and ATG arms, respectively) the information on death (and if yes, the main reason) and apparition of chronic GvHD has been collected in all centres involved in the INO107 study. Data were updated up to May 2018. The analysis performed with this new dataset was focusing on the primary composite criteria, the Overall Survival (OS) and the incidence of chronic GvHD.

### Inolimomab reduces by 43% the relative risk of death

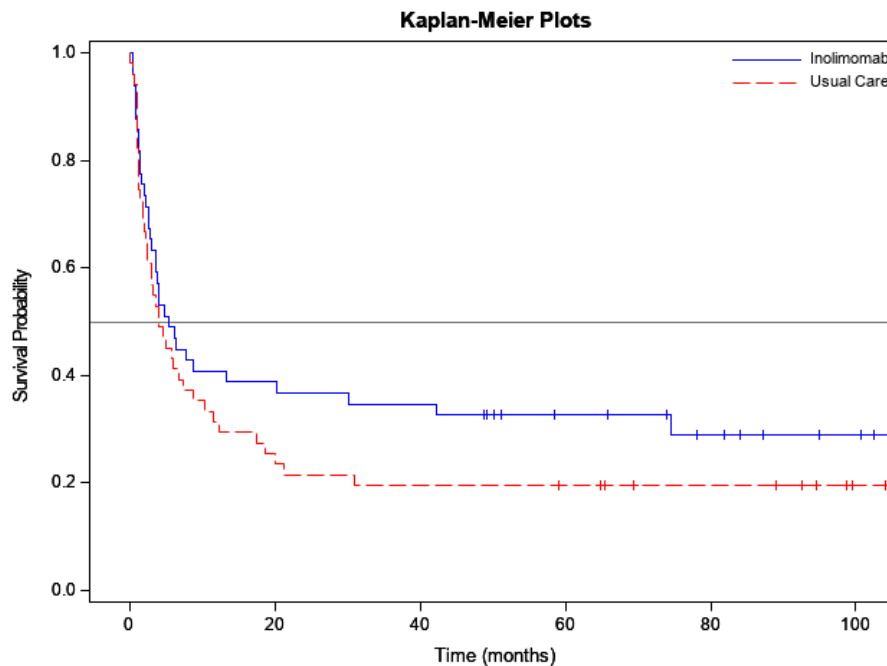
This long-term follow-up analysis has evidenced a positive outcome on composite primary endpoint at level of statistical significance set in the protocol (see detailed data page 2) but more importantly a very positive outcome on OS, which is the most robust endpoint of assessment in such life-threatening disease.

*“The Overall Survival endpoint was reached by 30.6% (15/49) patients and 19.6% (10/51) patients in the inolimomab and ATG arms, respectively. The adjusted HR (95% CI) was 0.572 (0.346, 0.947), two-sided  $p=0.030$ . This represents an absolute difference in survival of 11% in favour of inolimomab equivalent to relative reduction of 43% of risk of death. This analysis clearly demonstrates a clinical benefit of inolimomab and suggests that it may be a suitable therapeutic alternative in patients with grade II to IV SR-aGvHD.”* comments **Dr. David LIENS, Chief Medical Officer, ELSALYS BIOTECH.**

*“These additional data establish that the effect already noticeable at the end of the INO107 study, i.e. after a 1-year follow-up, is sustained over long-term period and show a clear clinical benefit of inolimomab in SR-aGvHD. These results are very encouraging and, together with the favourable safety profile, could ease the regulatory acceptance, at first in view of*

Compassionate Use, in France (ATU) and in other countries and then for market approval, both in Europe and in the USA.” Adds **Dr. Jacques MIZRAHI, VP R&D, ELSALYS BIOTECH.**

## Overall survival



### About inolimomab (LEUKOTAC<sup>®</sup>)

Inolimomab (LEUKOTAC<sup>®</sup>) 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  $\alpha$  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 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 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<sup>®</sup>), 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 founding shareholders are TRANSGENE and 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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