PRESS RELEASE

While ElsaLys continues to work on the filing of marketing approval in Europe and the U.S. for inolimomab, the company confirms the renew of its cohort ATU in France and compassionate use programs submissions in several other countries

- **During its first year under ATU and despite the pandemic, around 30 patients in France has been treated with inolimomab as it is considered a reliable treatment for acute cortico-resistant or corticosteroid-dependent graft-versus-host disease in adults and pediatric patients over 28 days of age.**
- **ElsaLys is working on expanding compassionate use programs for inolimomab in several other countries in Europe.**

Lyon, FRANCE, April 15, 2020, **ElsaLys Biotech** confirmed that The French National Agency for the Medicines and Health Products Safety (ANSM) has renewed the Temporary Authorisation for Use (ATU) so-called cohort ATU (cATU) for inolimomab (LEUKOTAC®) on December 24, 2020.

This renewed 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 is available to hematologists and physicians treating blood disorders and to hospital pharmacists for the treatment of acute cortico-resistant or corticosteroid-dependent graft-versus-host disease in adults and pediatric patients over 28 days of age. The indication should be discussed during a multidisciplinary consultation meeting. Inolimomab treatment can only be considered if the patient cannot be included in an ongoing clinical trial.

During its first year of administration under cATU and despite the pandemic, around 30 patients in France have been treated with inolimomab as it is considered a reliable treatment of this high-risk patient population.The number of patients included in the cohort ATU in France since December 2019 reflects a real medical need. This is the reason why ElsaLys is working on expanding compassionate use programs for inolimomab in a number of European countries. Several early access applications will be submitted.

" Inolimomab is already being administered in France before marketing autorisation in Europe and hopefully soon in other countries through compassionate use programs as it is considered a reliable treatment of this high-risk patient population with acute cortico-resistant or corticosteroid-dependent graft-versus-host disease." **said Dr. Christine GUILLEN, CEO and co-founder of ElsaLys Biotech.** *" Data on clinical benefit and safety profile we expect to collect through these compassionate use programs will support our work on the filing of marketing authorization applications (MAA) in Europe and in the U.S."*

About inolimomab

Inolimomab is an anti-IL-2 Rα monoclonal antibody active as an immunotherapy product for the treatment of steroid-refractory acute GvHD.

In acute GvHD, activated T cell lymphocytes from the allograft's donor recognize and attack recipient tissues. T cell lymphocyte activation and proliferation is governed by the key IL-2/IL-2 receptor (IL-2 R) pathway.

By recognizing the subunit α of the IL-2 Receptor complex (IL-2 Rα) which is upregulated on T cells upon activation, inolimomab blocks the binding of the cytokine IL-2 on IL-2 Rα thereby inhibiting IL-2 signalling and donor T cell proliferation.

The efficacy of inolimomab in aGvHD relies on its specific potent immunosuppression on T cell lymphocytes through the blocking of the IL-2/IL-2 Rα pathway triggering the disease.

Inolimomab received Orphan Drug Designation in Europe (March 2001) and in the U.S. (October 2002).

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 treatments, immunosuppressive treatments before allograft (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 acute GvHD episode).

Affecting between 30 to 50% of patients, GvHD is the main complication of hematopoietic stem cell transplantation. To halt this disease, physicians use corticosteroids. The fact remains that some 30 to 50% of aGvHD patients are refractory or dependent to the steroid treatment. To date limited therapeutic options are available for these patients with no standard treatment approved so far in Europe and only one in the US.

About ElsaLys Biotech

ElsaLys Biotech is a specialty pharmaceutical company, part of the Mediolanum Farmaceutici Spa group, focused on innovative medicines to address haemato-oncology related life-threatening and rare diseases.

Following strategic acquisitions and targeted developments, ElsaLys is establishing an immunotherapeutic portfolio focused on niche specialty pharmaceuticals to answer unmet medical needs.

Our commitment is to offer essential drugs meeting Public Health needs.

Founded in 2013, ElsaLys Biotech is located in the heart of the European cluster Lyon Biopole, in Lyon, France.

Stay in touch with ElsaLys Biotech and receive directly our press releases by filling our contact form on https://www.elsalysbiotech.com

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