Consortium including ElsaLys Biotech and Novadiscovery awarded €3.35 million by Bpifrance to advance inolimomab in graft-versus-host disease

- NOVA *awarded €2.4 million to leverage Jinkō®, its best-in-class clinical trial simulation platform, to conduct in silico studies for graft-versus-host disease*
- *Research academic teams of the consortium - Institut de Recherche Saint Louis[1] & Institut Mondor de Recherche Biomédicale [2] - to receive €0.95 million for their collaborative work with ElsaLys on in vitro and in vivo mechanisms of action of inolimomab*
- *ElsaLys Biotech utilising in silico studies to accelerate the European approval of inolimomab in both adult and paediatric populations with this rare and life-threatening disease*

Lyon, France – 19 January 2021: The Silikotac Program consortium, consisting of ElsaLys Biotech, Novadiscovery ("NOVA") and two expert academic teams from Hôpital St Louis (Paris) and Hôpital Henri Mondor (Paris), has been awarded €3.35 million in non-dilutive funding by Bpifrance to support development of inolimomab in graft-versus-host disease (GvHD), the main complication that may occur after an allogeneic hematopoietic stem cell transplantation. The ambition of the Silikotac Program is to create the first French industrial and scientific immunotherapy chain group focused on GvHD.

This financing is part of the PSPC (Projet de recherche et développement Structurant pour la Compétitivité) program fund from Bpifrance, a financing initiative from the French government to support new and emerging industries within France.

ElsaLys Biotech is a clinical stage company developing inolimomab, an immunotherapy product, for steroid-refractory acute graft-versus-host disease in adult and paediatric populations.

NOVA is a leading health tech company using *in silico* proprietary technology to optimize clinical trial development and predict drug efficacy. NOVA, which has been awarded €2.4 million, will conduct *in silico* clinical trials utilising its innovative Jinkō® platform. The results will be used to support future regulatory approval applications by ElsaLys for inolimomab in Europe. Jinkō® is NOVA's best-in-class clinical trial simulation and disease modelling platform. Its workflows are designed to closely resemble those of real-life clinical studies.

The two academic teams in the Silikotac consortium, from Institut de Recherche Saint Louis & Institut Mondor de Recherche Biomédicale, have been awarded €0.95 million to:

[1] Institut de Recherche Saint Louis, Pr Vassili Soumelis, Unité 976, Inserm and Université de Paris
[2] Institut Mondor de Recherche Biomédicale, Pr José Cohen, Unité 955, Inserm and Université de Paris Est Créteil

- Further deepen the *in vitro* mechanism of action of inolimomab at molecular and cellular level
- Evaluate new protocols for broadening and optimizing inolimomab use in the GvHD algorithm treatment using several *in vivo* preclinical models

ElsaLys announced in July 2020 the submission of a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for inolimomab for the treatment of Steroid-Refractory acute graft-versus-host disease (aGvHD) in grade II-IV adult patients. In Europe, the French National Agency for the Medicines and Health Products Safety (ANSM) granted a Temporary Authorisation for Use (ATU) for inolimomab renewed at the end of 2020. Inolimomab is therefore available in France to adults and paediatric patients over 28 days of age for the treatment of acute steroid-refractory or steroid-dependent graft-versus-host disease. Further early access applications will be submitted in other European countries while ElsaLys continues to work on the filing of marketing approval in Europe and the US.

Dr. Christine Guillen, CEO and Co-founder, ElsaLys Biotech, said: *"Patient numbers for rare diseases are limited and simulating clinical trials in a virtual population can help strengthen data packages submitted for regulatory approval. We are engaged, like regulatory agencies are, in using in silico trials for ethical concern and we think this approach can be key to accelerate the development of innovative drugs, notably in paediatric population."*

François-Henri Boissel, CEO, NOVA, said: *"We are excited to be leveraging Jinkō®, our unique simulation platform, to support ElsaLys in bringing an important treatment to patients. NOVA's mission is to help companies enhance their R&D activities and optimize outcomes for patients. The use of in silico trials is relatively new, but regulatory authorities are working towards providing a framework for expanded use as a third pillar of the R&D drug paradigm in addition to in vitro and in vivo approaches."*

Ends

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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.

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 directly receive our press releases by filling our contact form on www.elsalysbiotech.com

Follow us on Twitter: @ElsalysBiotech and on linkedin.com/company/elsalys-biotech/

About Novadiscovery

NOVA is a leading health tech company using *in silico* clinical trials to predict drug efficacy and optimize clinical trial development. The Company aims to improve R&D productivity and maximize patient outcomes by predicting the clinical benefit of a potential new drug candidate through computer simulation, ahead of human trials.

NOVA's innovative approach leverages disease modeling and simulation expertise accumulated over the past decade and combines mathematical models of diseases and potential new treatments with virtual patients in its integrated clinical trial simulation platform, Jinkō®.

NOVA is headquartered in Lyon, France and has a team of 40 scientists, engineers & clinicians who work at the interface of biology, pharmacology, mathematics & computer science.

For more information, please visit https://www.novadiscovery.com and follow us on Twitter @novadiscovery and linkedin.com/company/novadiscovery