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LYSA and GLA launch MorningLyte, an international randomized phase III clinical study comparing a treatment combining a CD20xCD3 T-cell engaging bispecific antibody and Lenalidomide to standard immunochemotherapy in patients with previously untreated follicular lymphoma.

This press release announces the launch of the "MorningLyte" international clinical trial, a joint initiative of the LYSA/LYSARC (France, Belgium, Portugal) and GLA (Germany) groups. This randomized, multi-center Phase III trial is designed to compare the efficacy of a new treatment for patients with previously untreated follicular lymphoma. This treatment combines a bispecific T-cell-engaging antibody (mosunetuzumab) with an immunomodulator (lenalidomide), comparing it to conventional immunochemotherapy.

Follicular lymphoma, the second most common type of B lymphoma, is usually treated with a combination of chemotherapy and an anti-CD20 monoclonal antibody. However, despite this approach, many patients relapse, and current treatments are associated with significant short- and long-term side effects. The MorningLyte study aims to offer a "chemotherapy-free" alternative, with the hope of reducing relapses and improving patients' quality of life.

Key figures:

- The study will include **790 patients** in 8 countries: France, Belgium, Portugal, Germany, Spain, Switzerland, Japan and Austria.
- The recruitment phase will last **3 years**, and patients will be followed for a total of **10 years**.
- **50 patients** have already been recruited in France and Belgium.

This project is supported by academic cooperative groups such as GELTAMO (Spain), SAKK (Switzerland), AGMT (Austria), and the Roche laboratory. A parallel study will be carried out in Japan in partnership with Chugai, the sponsor for this country. The main aim is to demonstrate that treatment without chemotherapy can be more effective than conventional immunochemotherapy, by prolonging remission while reducing toxicity.

This study is a crucial new step following previous trials conducted by LYSA, such as PRIMA and RELEVANCE. The initial results of the MorningLyte study are eagerly awaited, as it could transform the standard of treatment for first-line follicular lymphoma, some 20 years after the introduction of the first immunochemotherapies.

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