



#### **ASH 2021:**

## LYSA and LYSARC to present their significant advances in lymphoma research

LYSA and LYSARC, author of numerous publications and sponsor of recognized clinical trials, are major players in lymphoma research. They will attend the 63rd Annual Meeting of the American Society of Hematology (ASH). This year, scientific output and studies sponsored by LYSA and LYSARC are particularly highlighted. Indeed, the group will present 17 abstracts in both oral and posters communications.

## The excellence of French and Belgian academic research on lymphomas

LYSA and LYSARC represent a 20 years long, independent clinical research network specializing in lymphomas and collaborating with countless scientific teams at the international level. They gather more than 500 professionals and bring together 90 care centers spread over 3 countries (France, Belgium and Portugal)

"This year, LYSA and LYSARC are proud to present 11 oral presentations and 6 poster presentations on the occasion of the notorious annual meeting on hematology: ASH 2021 in Atlanta."

Franck Morschhauser, President of LYSA and LYSARC

#### Multiple collaborative methods to deliver therapeutic innovations for the benefit of patients

Recognized for their outstanding work in clinical trial conduct: from diagnostic and prognostic research to bedside treatment implementation and routine practice guidelines the cooperative group LYSA and its operational structure LYSARC have proven to be key players in lymphoma research. Their various partnerships and collaborations have allowed to combine resources, risks, and responsibilities to form a benchmark for clinical studies, resulting in the identification of new treatments and efficient therapeutic strategies. "Ranging from academic, clinical studies, such as MCL-R2, to real-time databanks, like DESCAR-T, which gave rise to unique collaborations between cooperative and industrial groups and health authorities, to clinical studies in public/private partnership, such as POLARIX with ROCHE laboratories, LYSA/LYSARC have distinguished themselves by making it a point of honor to work in collaboration with all the current health players," Franck Morschhauser affirms.

# Focus on 3 different collaborative models leading to major oral communications in terms of changes to and validation of therapeutic practices

## POLARIX: a study in partnership with the Roche laboratory

Presented as a Late Breaking Abstract and during an ASH media briefing

POLARIX is an international, randomized, double-blinded, phase 3 study evaluating the efficacy and safety of the pola-R-CHP combination, including polatuzumab vedotin, the new monoclonal antibody drug conjugate, in association with rituximab and CHP (cyclophosphamide, doxorubicin and prednisone), in comparison with the standard R-CHOP treatment (rituximab + cyclophosphamide, doxorubicin, vincristine and prednisone) in use for twenty years for patients with diffuse, large B cell lymphomas (DLBCL).

Primary analysis of this study shows that the pola-R-CHP combination reduces the risk of disease progression, relapse or death by 27% compared to R-CHOP in first-line DLBCL patients. This new combination does not show more side effects than those from R-CHOP. These results suggest that this new combination could now be considered as a first-line treatment for these patients.

LYSA and LYSARC and Roche have combined their skills to offer new therapeutic combinations for the benefit of patients. The associations (LYSA and LYSARC) bring their expertise in the treatment of lymphomas, the identification of clinical situations with an unmet medical need and the conduct of clinical trials; whilst Roche brings its expertise in the development of new, therapeutic solutions for patients.





## MCL-R2 Elderly: an academic study

This phase 3 study has been monitoring the efficacy of an induction immunochemotherapeutic treatment of the R-CHOP + R-HAD type, versus R-CHOP alone, followed by maintenance treatment with lenalidomide + rituximab, versus rituximab alone, on elderly patients with Mantle Cell Lymphoma

"Following on from the study held by the European Mantle Cell Lymphoma group, MCL Network, on patients aged over 60, who have shown the efficacy of an induction treatment with R-CHOP, followed by maintenance treatment with rituximab, the MCL Network and LYSA/LYSARC have carried out the MCL-R2 Elderly trial, aiming to evaluate the efficacy and tolerance of initial treatment with R-CHOP+R-HAD, versus R-CHOP alone, followed by maintenance treatment with lenalidomide + rituximab, versus rituximab alone." Dr Vincent Ribrag, Head of the Hematology department at the Gustave Roussy Institute, Villejuif and Professor Marie-Hélène Delfau, Head of the Hematology and Biological Immunology department at the Henri Mondor Hospital, Créteil AP-HP.

The main objective of this study, held in partnership with the MCL Network and the industrials, Bristol Myers Squibb and Roche, was to assess whether the association of lenalidomide with rituximab during maintenance would improve Progression Free Survival. To do so, patients sensitive to induction treatment received, after randomization, one of the two maintenance treatments (rituximab alone or in combination).

623 patients had been recruited over the whole study at 115 investigating centers spread over 7 European countries and 495 patients received one maintenance treatment.

The initial clinical and biological results from the study will be presented at ASH 2021.

### **DESCAR-T**: the French CAR T registering and monitoring scheme.

In 2019, the French National Authority for Health (HAS) asked industrial companies to implement a real-time monitoring register of all patients treated with CAR T cells in France. This French national register, called DESCAR-T, is a unique model in today's clinical research environment, bringing together experts from several hemopathies around the same type of treatment, CAR T cells. This register is the result of a collaboration between several groups of academic cooperators, dedicated to clinical research; LYSA, GRAALL, SFCE, SFGM-TC and the IFM it being supported by the industrials concerned: Gilead, Novartis, and in the near future, Bristol Myers Squibb.

DESCAR-T allows via a common register to provide responses requested and crucial for health authorities, industrials and scientists regarding the use, efficacy and undesirable effects of such treatments. From now until the end of 2021, the 35 French centers qualified in CAR-T will take part in DESCAR-T: 50 to 60 patients are registered every month in the register.

"Scientific work carried out on the basis on the DESCAR-T register is generating a lot of interest in the international, scientific community, as can be gathered from the three speeches at the ASH meeting (American Society of Hematology). It is also a wonderful example of collaboration between our health authorities, industrials and groups of academic collaborators."

Professor Roch Houot, Head of the Hematology Department at the CHU in Rennes, DESCAR-T coordinator

## List of the 11 oral communications to be presented

#### 1 late-breaking speech on results from the POLARIX study:

• LBA-1 The POLARIX Study: Polatuzumab Vedotin with Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (pola-R-CHP) Versus Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (R-CHOP) Therapy in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma

Hervé Tilly, Henri Becquerel Center, Rouen

## 2 speeches in collaboration with the MCL Network, on the MCL R2 study:

<u>Rituximab-Lenalidomide (R2) maintenance is superior to rituximab maintenance after first-line Immunochemotherapy in Mantle Cell Lymphoma: results of the MCL R2 Elderly clinical trial by Vincent Ribrag, Gustave Roussy Institute, Villejuif
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Impact of Maintenance Arm on Prognostic Value of MRD after Induction Treatment in MCL R2
 Elderly Trial, a Mantle Cell Lymphoma Network Study Marie-Hélène Delfau, Henri Mondor Hospital, Créteil

#### 3 speeches arising from DESCAR-T are to be presented:

• CAREL: Outcome of relapsed/refractory aggressive B-cell lymphoma patients relapsing after anti-CD19 CAR T-cells and enrolled on the DESCAR-T French national register

Roberta di Blasi, Saint-Louis Hospital, Paris

• <u>A Propensity Score-Matched Comparison of Axi-Cel and Tisa-Cel for Relapsed/Refractory Diffuse</u>
<u>Large B-Cell Lymphoma in Real-Life: A LYSA Study from the Descar-T Register</u>

Emmanuel Bachy, Lyon-Sud Hospital Center, Pierre-Bénite

• Kte-X19 in Relapsed or Refractory Mantle-Cell Lymphoma, a "Real-Life" Study from the Descar-T Register and Lysa Group

Charles Herbaux, Montpellier Hospital Center

## 5 clinical/ancillary/retrospective studies

• <u>Salvage Therapy with Brentuximab-Vedotin and Bendamustine for Patients with Relapsed/Refractory T Cell Lymphoma. a Multicenter and Retrospective Study</u>

Krimo Bouabdallah, Bordeaux Hospital Center, Pessac

• <u>Nivolumab First-Line Therapy for Elderly, Frail Hodgkin Lymphoma Patients: Niviniho, a Lysa</u> Phase II Study

Julien Lazarovici, Gustave Roussy Institute, Villejuif

• <u>Total Metabolic Tumor Volume and Tumor Dissemination are independent prognostic factors in</u>
Advanced Hodgkin Lymphoma

Salim Kanoun, IUCT Oncopôle, Toulouse

• Chromatin Accessibility Profiling to Increase Diagnostic Accuracy and Refine Cell of Origin Classification of Mature T-cell Lymphoma

Edith Julia, Lyon-Sud Hospital Center, Pierre-Bénite

• The Eatl-001 Trial: Results of a Phase 2 Study of Brentuximab Vedotin and CHP Followed By Consolidation with High-Dose Therapy – Autologous Stem-Cell Transplantation (HDT-ASCT) in the Frontline Treatment of Patients with Enteropathy-Associated T-Cell Lymphoma

David Sibon, Necker Hospital, Paris

#### 6 LYSA abstracts retained for poster presentations

• <u>Final Analysis of a Prospective Multicenter Phase II Trial of the Lymphoma Study Association</u> (LYSA) Using Prednisone, Vinblastine, Doxorubicin and Bendamustine (PVAB) Regimen in First-Line Therapy for Patients over 60 Years with Advanced-Stage Classical Hodgkin Lymphoma

Hervé Ghesquières, Lyon-Sud Hospital Center, Pierre-Bénite

• Six-Year Results from the Phase 3 Randomized Study Relevance Show Similar Outcomes for Previously Untreated Follicular Lymphoma Patients Receiving Lenalidomide Plus Rituximab (R2) Versus Rituximab-Chemotherapy Followed By Rituximab Maintenance

Franck Morschhauser, Lille Hospital Center

 Breast Implant Associated-Anaplastic Large-Cell Lymphoma (BIA-ALCL): Data Based on the Lymphoma Study Association (LYSA) Register. Promising Results of Brentuximab Vedotin Combined with Cyclophosphamide, Doxorubicin and Prednisone (BV-CHP) As First-Line Treatment for Patient Requiring Chemotherapy





Fabien Le Bras, Henri Mondor Hospital, Créteil

• <u>Single-cell and spatial analyses characterize distinct subsets of malignant T cells in angioimmunoblastic T cell lymphoma</u>

François Lemonnier, Henri Mondor Hospital, Créteil

• <u>Selinexor in Combination with R-GDP for Patients with Relapsed/Refractory B-Cell Lymphoma:</u> <u>SELINDA phase lb LYSA Study</u>

Marie Maerevoet, Jules Bordet Institute, Brussels, Belgium

• A Molecular Classifier Increased the Accuracy of Lymphoma Diagnosis By Expert Pathologists in the Diffuse Large B-Cell Lymphoma Gained Trial from the LYSA

Amine Moslemi, Amiens Hospital Center

#### PRESS CONTACTS

LYSARC: Amel BOUAKAZ, Head of Communications, amel.bouakaz@lysarc.org I 06 76 93 86 61

#### **About lymphomas**

Lymphomas are cancers of the lymphatic system. They represent the most common hemopathy, accounting for about half of blood cancers. These are disparate illnesses, with more than 80 sub-types of lymphoma, making diagnosis difficult and requiring differing treatments. They are divided into Non-Hodgkin Lymphoma (NHL) and Hodgkin Lymphoma (HL). Lymphomas can affect all ages (including children), are mainly ganglionic, yet can affect (only or as an accompaniment to) all organs. There is no prevention, nor screening. Its incidence has doubled in 30 years, with currently 18,000 new cases diagnosed in France.

#### LYSA: a network of clinical research professionals

LYSA is a cooperative, academic group and a non-profit organization, an international leader in clinical research and translational on lymphomas. It groups together more than 500 medical members, researchers and experts, distributed over 90 clinical centers in three countries (France, Belgium and Portugal). LYSA's aim is to assemble professionals, who specialize in the field of lymphomas, to promote basic and clinical research, improve prevention, the care and treatment of patients and promulgate knowledge about this cancer. It collaborates with numerous scientific teams around the world in the understanding and treatment of lymphomas.

## LYSARC: the academic research organization linked to LYSA

LYSARC is LYSA's operational body, allowing the conduct of clinical research on lymphomas at the international level. LYSARC has available to it all those integrated functions and platforms devoted to the pathology, biology and imaging tests to run multiple clinical studies of phases 1 to 4 on lymphomas every year and registers, in its role as promotor. This non-profit organization is scientifically independent and pools more than 130 highly-qualified staff (doctors, pharmacists, biologists, engineers and MBAs).

lymphoma-research-experts.org