European LeukemiaNet

PROMYSE
A pan-European registry for relapsed Acute Promyelocytic Leukemia patients

APL is the first subtype of acute leukaemia for which a range of molecularly targeted therapies are available and which have contributed to its relatively favourable prognosis. Indeed, after the discovery of differentiation therapy and the introduction of ATRA in combination with cytotoxic agents, management of newly diagnosed patients can rely on well established protocols which allow to cure at least 75% of cases.

More recently, the advent of Arsenic Trioxide (ATO) has offered a highly effective and reasonably safe therapeutic strategy for relapsed/refractory APL. This agent can in fact induce second molecular remission in approximately 80% of patients who relapse after ATRA and chemotherapy. Although a consensus exists on using at least two cycles of ATO to re-induce molecular CR after relapse, the continuation of therapy in these patients is subject to a number of variables which include both patient (age, performance status, donor availability) and disease-related parameters (duration of first CR, PCR status, etc.).

As different treatment options for relapsed APL are now available, a European team of experts in the management of APL has identified the need to assess their efficacy and safety in order to assess the most suitable therapeutic strategies by patient group. This is the rationale for the creation of PROMYSE.

PROMYSE is a prospective registry to assess the treatment of relapsed APL patients across Europe. Given the rarity of this disease and the limited number of patients relapsing after first-line therapy, it is essential that such study is implemented on a pan-European basis to ensure a sufficient number of patients are included in a reasonable period of time.

The Registry is based on Case Report Forms drafted by a European panel of APL experts, made available in electronic format (eCRF) and consisting of the following six modules:

1. **Registration and Data at first Diagnosis of Relapsed APL:**
   - **Data at Primary Diagnosis**
   - **Previous Treatments.**
2. **Salvage Therapy of Relapsed APL:**
   - **Induction**
   - **Patient Status at Initiation of Therapy**
   - **Induction Therapy, Concomitant Treatments**
   - **Final Evaluation and Toxicities.**
3. **Salvage Therapy of Relapsed APL**
   - **Consolidation.**
4. **Salvage Therapy of Relapsed APL:**
   - **Post-consolidation, Including Allogeneic**
   - **Autologous SCT, ATO**
   - **Chemotherapy based regimens.**
5. **Salvage Therapy of Relapsed APL:**
   - **Follow up**
   - **Patient Status after end of Salvage Therapy.**
6. **Salvage Therapy of Relapsed APL:**
   - **SAE description and Causal Relationship.**

The eCRF can be accessed through a dedicated secured web-site (www.promyse.net) and is simple to use. After becoming familiar with it, participants will have the possibility to access, verify, enter and modify data from any work-station connected to the Internet.

The Promyse Steering Committee members are:
- Pierre Fenaux, Hopital Avicenne (AP-HP)/Université Paris 13
- Eva Lengfelder, III Medizinische Klinik Universitätsklinikum Mannheim
- Francesco Lo Coco, Policlinico Tor Vergata/Roma
- Miguel Sanz, University Hospital La Fe/Valencia

A team of Coordinators has been established, with the task of facilitating the registry access to hematologists interested to participate in PROMYSE.
Depending on your country, please contact the corresponding Coordinator to get more information:

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ELN European LeukemiaNet

www.leukemia-net.org

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