EuroBloodNet sponsoring Clinical Trials and promoting innovative therapies

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EuroBloodNet
Association

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- *What we do*
  - Generally « niche » trials that are not explored by pharma companies
  - EuroBloodNet Association will be the sponsor and will do the trial submission on CTIS
  - Cooperation and funded by industrial partners
  - Involving several countries in the European Union

- *Current trials*
  - Satisfy (A Glenthoj, E Van Beers, T Doeven): Mitapivat in rare inherited anemias
  - Luspara (T Leblanc) : Luspatercept in rare inherited anemias

- *Open to new collaborations*

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CTIS - Clinical Trial Information System

- *Centralised platform for the submission, authorisation and supervision of clinical trials in the EU and the European Economic Area*
  - Preparation and soumission of Part I (scientific) and Part II (ethical) documents
  - Assessment by National regulatory authorities
  - Q&A phase: authorities may request informations and modifications
  - Regulatory decision

- *Once approved, the trial can start*
  - Inclusion of patients
  - Monitoring of centres and compliance with the protocol
  - Reporting adverse events

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LUSPARA - Luspatercept in patients affected with rare inherited anemias:

- *6 centres involved in France and Italy:*
  - 5 centres in France (Lille -Saint-Vincent de Paul , CHU Montpellier , Paris Saint Louis , Paris Necker, Bordeaux)
  - and 1 in Italy (Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico di Milano)
- *45 patients to be enrolled*
- *Study duration - 42 months incl.*
  - 24 months for the inclusion period
  - and 52 weeks treatment period
- *Study funded by BMS*
- *Authorisation received by National Health authorities and and ethics committees*

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European Reference Network | Hematological Diseases (ERN EuroBloodNet)

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Thank you!

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