Gilles DULUC
Directeur de la Recherche Clinique et de l'Innovation

Jeanne PATARD
Directrice adjointe de la Recherche Clinique et de l'Innovation

Département Promotion Interne

Anne GIMBERT
Responsable
Tél 05.57.82.04.34
anne.gimbert@chu-bordeaux.fr

Talence, le 13/05/2025

Object : Interventional Clinical Trial's results posting to the European Clinical Trail register (EudraCT) of the European Medicines Agency (EMA).
In accordance of Directive 2001/20/CE
Study Title : MUCOLAX : Effect of polyethylene glycol treatment on intestinal inflammation associated with cystic fibrosis in children.
EudraCT Nbr : 2019-004958-29
Sponsor Nbr : CHUBX2019/25
Transitioned study to the Regulation (EU) 536/2014 : no
Status of the study : prematuraly ended study

At the time the MUCOLAX study started (2019), the marketing authorization for lumacaftor-ivacaftor concerned cystic fibrosis patients over 12 years of age with the homozygous DeltaF508 mutation, i.e. around 30% of patients followed at the Bordeaux and Toulouse university hospitals.

On december 2019, the market authorization was extended to the indication of lummacaftor-ivacaftor for children aged 2 and over. On July 2021, a market authorization was obtained for the elexacaftor-tezacaftor-ivacaftor combination, a modulator that concerns all patients aged 12 and over, with the heterozygous DeltaF508 mutation.

As a result nearly 80% of cystic fibrosis patients were covered by a modulator, and this number rose to 90% by the end of 2022, as the marketing authorization for elexacaftor-tezacaftor-ivacaftor has been extended to 6-11 year-olds, leading the feasibility unfeasible.

Finally the study was stopped prematurely on 18/05/2022.

For the Head of the University Hospital of Bordeaux
and by delegation,
The Director of the Clinical research and Innovation

Gilles DULUC

by delegation

Anne GIMBERT
Responsable Promotion Interne
Direction de la Recherche Clinique et de l'Innovation