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Talence, le 12/05/2025

Object : Interventional Clinical Trial's results posting to the European Clinical Trial register (EudraCT) of the European Medicines Agency (EMA).
In accordance of Directive 2001/20/CE

Study Title : REPSORA : Profiling leukocytes subpopulations in peripheral blood and skin lesions of responders and non responders under efalizumab (anti-CD11A) treatment of psoriasis

EudraCT Nbr : 2008-004721-41

Sponsor Nbr : CHUBX2008/08 / **Afssaps Nbr** : A80769-50

Transitioned study to the Regulation (EU) 536/2014 : no

Status of the study : prematuraly ended study

Following the recommendation of the European Medicines Evaluation Agency (EMEA) to suspend the marketing authorization of RAPTIVA® (efalizumab) on February 19, 2009, and taking into account:

- the risk of progressive multifocal leukoencephalopathy and other serious adverse events in patients exposed to efalizumab, neurological events such as Guillain-Barré and Miller-Fischer syndromes, encephalitis and encephalopathy, and infectious events such as sepsis and opportunistic infections;
- the benefit/risk ratio of the product in its current indication has become unfavorable;
- the absence, at this stage of product development, of data enabling the identification of a group of patients for whom the benefits would outweigh the risks;

In this context the benefit risk ratio of the study became unfavorable and the steering committee took the decision to end the study.

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

Gilles DULUC
par délégation Jeanne Pakard, directrice adjointe