



**Laboratoires S.M.B. S.A.**

AN INTEGRATED PHARMACEUTICAL COMPANY

25<sup>th</sup> March 2021

**RE : SMB-NAL-III-09-1 Study in Cystic Fibrosis**

“A Phase III, Multi-centre, Randomised, Placebo-controlled, Double-blind Study of the Incidence of Recurring Pulmonary Exacerbations in Cystic Fibrosis Patients using Two Different Doses of Inhaled Nacystelyn”

---

The clinical trial NAL-III-09-1 was declared as prematurely ended on the 15<sup>th</sup> of October 2010 prior inclusion of any subject in the trial.

The underlying reason was submitted with the prematurely end of trial notification: significant and unscheduled stability problems were noticed with the batches of NAL 5mg and 10mg capsules that were scheduled for use in this study. As these issues cannot be resolved in the short term, it was decided to terminate the study prematurely.

No subject were included in the trial.

For this reason, there is no results to communicate and include on the EudraCT results website. No statistical analysis can be provided.

---

Rue de la Pastorale 26-28 Herdersliedstraat  
BRUXELLES B-1080 BRUSSEL  
Belgium  
Tel. : +32 (2) 411 48 28  
Telefax : +32 (2) 411 28 28

CBC Banque  
N°Swift  
Fortis  
C.C.P.-P.C.R.  
T.V.A. - B.T.W.  
R.P.M. - R.P.R.

194-0128311-77  
CREGBEBB  
210-0392580-73  
000-0985993-85  
BE 0.418.956.361  
Bruxelles