

## Letter of study termination

Milan, 12/10/2022

Full Title of the KLS0118 trial: "Randomised, single dose, placebo-controlled, double-blind, parallel group study to evaluate the onset of pain response after administration of ketoprofen lysine salt 40 mg, in male and female subjects with acute pain after removal of a molar tooth" - EudraCT Number 2019-002114-38.

Dear Sirs,

We are writing to inform you that the sponsor Dompé S.p.A. has decided to prematurely end the KLS0118 clinical trial of OKi® (Ketoprofen lysine salt 40 mg granules for oral solution).

The trial started on 05MAR20 (FPFV) was temporarily withdrawn due to COVID emergency. The study re-started on 02OCT20 with a very low enrolment rate. As the overall delay could not ensure a proper data integrity and the slow enrolment rate did not ensure to complete the recruitment within JUL21, the Sponsor decided to prematurely terminate the study. The small sample did not allow any efficacy analysis other than listing individual data.

For the above reasons, the premature end of the study is based on the sponsor's voluntary, business-related decision.

If you have any questions or require additional information, please contact dr. Maria De Pizzol, email: [maria.depizzol@dompe.com](mailto:maria.depizzol@dompe.com)

We are asking for your kind relevant actions.

Kindest regards

DocuSigned by:  
  
C6AA6C5F233A43F...

Maria De Pizzol  
Head of Global Clinical Operations, Senior Director