



PIV European Unit-study close out

Date: Aug 13, 2021

To whom it may concern,

Sponsor: Ansun Biopharma Inc.,

Subject: Prematurely Ended EU Clinical Trial and Trial Results

EudraCT No.	Protocol Title	Sponsor Code
2018-004318-16	A Phase III Randomized Placebo-Controlled Study to Examine the Efficacy and Safety of DAS181 for the Treatment of Lower Respiratory Tract Parainfluenza Infection in Immunocompromised Subjects	DAS181-3-01

The global clinical trial DAS181-3-01 terminated early in all EU member states on 18 November 2020.

The reason for the early termination in EU member states was due the drop in the detection of parainfluenza virus detected in the Autumn of 2019 that continued through 2020, most likely due to the health measures implemented globally to combat the COVID-19 pandemic. The disruption on the parainfluenza virus severely impacted the ability to recruit patients for this clinical trial and therefore it was decided to terminate the DAS181-3-01 clinical trial in the European Union.

No patients were ever enrolled in any of the EU member states.

The early termination of the clinical trial in EU member states will not affect evaluation of the final clinical trial results, nor have any impact on the risk assessment of the investigational medicinal product.

The delay in publishing the global clinical trial results for DAS181-3-01 is due to the impact of COVID-19 on recruitment and hence, the completion of the study.

The final clinical trial data has not yet been collated. It is anticipated that the final clinical trial results will be available in Q4 2023, and subsequently published on [clintrials.gov](https://www.clinicaltrials.gov). We will provide an update to the EMA when this is completed.

Yours Sincerely,

Jennifer Ho, MD, PhD
SVP, Clinical Development & Operation