Clinical trial results:
Phase I/II, Open-Label, Dose Escalation Study of the Safety, Pharmacokinetics, and Pharmacodynamics of NV1205 in Pediatric Male Subjects with Childhood Cerebral Adrenoleukodystrophy (CCALD)

Summary

EudraCT number	2017-001684-21
Trial protocol	FR GB
Global end of trial date	17 December 2019

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	NV1205-009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Neurov Acquisition LLC
Sponsor organisation address	20, Park Plaza, Suite 1200, Boston, MA, United States, 02116
Public contact	President/Managing Director, Neurov Acquisition LLC, +1 617778 2500, alevin@racap.com
Scientific contact	A Levin, Neurov Acquisition LLC, +1 617778 2500, alevin@racap.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	

Is this the analysis of the primary completion data?	Yes
Global end of trial reached?	Yes
Global end of trial date	17 December 2019
Was the trial ended prematurely?	Yes due to the sponsor deciing not to proceed with study

Notes:

General information about the trial

Main objective of the trial:

Primary:
To evaluate the safety and pharmacokinetics of NV1205 in pediatric subjects diagnosed with CCALD.

Protection of trial subjects:

Not applicable as no subjects were enrolled in the study and the study terminated early in December 2019.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 August 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Notes: No subjects were enrolled in the study in either France or United Kingdom. Early termination/end of trial notifications were sent to both ANSM and MHRA in December 2019 and acknowledged, alongside the respective Research Ethics Committees/study sites.

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were enrolled in either UK or France and the study was terminated early in December 2019.

Pre-assignment

Screening details:

Not applicable

Baseline characteristics

End points

End points reporting groups

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Assessment type	

Dictionary used

Dictionary name	
Dictionary version	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No results are available as no patients enrolled in the study and the study was terminated.

Notes: