

20th May 2022

Dear Sirs/Madams,

The clinical trial – AM-111-CL-15-01 - was prematurely discontinued in 2018 while recruitment was still low (56 out of the planned 300 subjects).

EudraCT number	Sponsor code	Title	Sponsor
2016-005166-58	AM-111-CL-15-01	Efficacy and Safety of AM-111 as Acute Sudden Sensorineural Hearing Loss Treatment (ASSENT)	Auris Medical Inc.

The study was submitted and approved in Belgium and Czech Republic. However, recruitment was never initiated in those countries. We therefore consider that no posting of study data is required on EudraCT.

Information on the partial results from U.S. and South Korea are available in clinicaltrials.gov.

<https://clinicaltrials.gov/ct2/show/results/NCT02809118?term=AM-111&draw=2&rank=1>

Kind regards,



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