Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA)

SCIENTIFIC COMMITTEE MEMBERS AND EXPERTS

I, Peter Munch Andersen

Organisation/Company: N/A

Country: Netherlands

Declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

1.1 Employment

No interest declared

1.2 Consultancy

Time Period	Start Date	End Date	Name of pharmaceutical company	Type	Product name	Therapeutic indication	General role / Area of activity
Current	01-01-2014	22-03-2023	Biogen Idec	Individual product related	tofersen (VALOR, ATLAS trials)	antisense oligonucleotide genetherapy targeting the SOD1 gene in familial ALS	null
Current	01-01-2023	22-03-2023	Lundbeck	Individual product related	preclinical work for developing new anti	ALS	null
Current	01-01-2020	22-03-2023	Regeneron	Cross product related/ general (non product related)	null	null	developing new drugs against SOD1_mediated ALS. In preclinical phase.
Current	01-01-2022	22-03-2023	uniQure	Cross product related/ general (non product related)	null	null	preclinical phase developing genetherapy drugs targeting C9orf72HRE_mediated ALS and FTD.
Past	01-01-2016	01-12-2019	Orphazyme	Cross product related/ general (non product related)	null	null	phase_3 clinical drug trial design for testing the chaperone_inducer arimoclomol in ALS (the ORARIALS_01 and ORARIALS_02 studies)
Current	01-01-2019	22-03-2023	Avrion	Individual product related	development of siRNA genetherapy	SOD1_mediated familial ALS	null
Current	01-01-2022	22-03-2023	VectorY	Cross product related/ general (non product related)	null	null	preclinical phase of developing an array of drugs for ALS and dementia

1.3 Strategic advisory role

No interest declared

1.4 Financial interests

No interest declared

1.5 Principal investigator

Time Period	Start Date	End Date	Name of pharmaceutical company	Product Name	Therapeutic indication
Past	01-01-2018	01-12-2022	Orion Pharma	levosimendan	ALS
Current	01-01-2020	22-03-2023	AB Science	masitinib	ALS
Current	01-01-2022	22-03-2023	Sanofi	SAR443820 (Himalaya study)	all types ALS
Current	01-03-2022		Amylyx	Albrioza	ALS, National Principal Investigator in Sweden for the ongoing PHOENIX and PHOENIX OLE phase 3 trial
Current	01-01-2022	22-03-2023	Sanofi	SAR443820 (Himalaya study)	all types ALS
Current	01-01-2014	22-03-2023	Biogen	Tofersen	SOD1_genetherapy for familial ALS (ATLAS since 2021, ongoing clinical trial in presymptomatic carriers of pathogenic SOD1 mutations)
Past	01-01-2020	01-12-2022	Alexion	ravulizumab	ALS
Current	01-01-2022	22-03-2023	AL_S Pharma	AP101_02 (phase 2 study testing monoclon	ALS

1.6 Investigator

Time Period	Start Date	End Date	Name of pharmaceutical company	Product Name	Therapeutic indication
Current	01-03-2022	22-03-2023	Amylyx	AMX0035 Phase_3 PHOENIX trial	ALS (all types)

1.7 Grant / Funding to organisation /institution

No interest declared

1.8 Close family member interest

No interest declared

1.9 Repurposing of a medicinal product

No interest declared

1.10 Any other interests or facts

Investigator_Initiated Trial with prof D. Lange, Cornell University NY as PI repurposing pyrimethamine as a novel treatment for ALS: Phase 1 and _2 trials 2007_2016. 2001_2018 member of the Regional Medical Research Ethics Committee in Umeå (reviewing grant applications including drug trials (all phases) performed at hospitals across northern Sweden). Since 2006, I author the ALS Care Guidelines document on behalf of the Swedish Board of Health: This document includes sections on all aspects of ALS clinical management including use of medications. I receive compensation for this work. From 2003_2015 I was the chairman of the EFNS task force for writing four evidence_based consensus guidelines papers on the clinical management and treatment of ALS. Since 2016, I am a board member of the EAN's work group preparing similar new guidelines (to be published later this year). These guidelines also include recommendations for therapies. The EFNS and EAN work was/is done independently of industry and no consultancy fee is given. If approved by the Swedish Ethical Committee and MPA, IONIS Pharmaceutical

ION363CS1 (ASO against familial ALS caused by mutations in the FUS gene) and PTC Pharma's CARDINALS (phase 2 study pf PTC857) will begin in Sweden later in 2023.

1.11 Committee for Advanced Therapies (CAT) member or alternate

Not a CAT member or alternate

2.1 Employment

No interest declared

2.2 Consultancy

No interest declared

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

No interest declared

2.6 Investigator

No interest declared

2.7 Grant / Funding to organisation /institution

No interest declared

2.8 Close family member interest

No interest declared

2.9 Any other interests or facts

No interest declared

CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality as long as the information or document has not been made public/is not in the public domain.

- Not to disclose (or authorise any other person to disclose) in any way to any third party [1] any Confidential Information or Confidential Document.
- Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
- To dispose of Confidential Documents as confidential material as soon as I have no further use for them.
- When expressing views to indicate clearly that the views are my own if acting in my own capacity or those of the EMA, Management Board, Committee, Working Party, Expert Group or other group if acting on behalf of that group.
- Not to disclose any commercially confidential information.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate and complete to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

1. Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

Full Name:	Peter Munch Andersen
Date:	2023-09-19

For definitions of activities etc, refer to the policy on handling of competing interests.