EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Public Declaration of Interests and Confidentiality Undertaking of European Medicines Agency (EMA), Scientific Committee members and experts

## Public declaration of interests

I, Yann Le Cam

Organisation/Company: Eurordis

Country: France

do hereby 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:

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

| Company | Subject Matter |
|---|---|
| ACTELION - a Janssen pharmaceutical company of J&J; Alexion Services Europe; Alnylam Netherlands BV; Bertarelli Foundation; Biogen (Czech Republic) s.r.o.; Chiesi Farmaceutici S.p.A.; CSL BEHRING; Cytokinetics, Inc.; Horizon Therapeutics; Ovid Therapeutics; ProQR; Recordati Rare Diseases; Roche; Swedish Orphan Biovitrum BVBA; Vifor Pharma Group; VOZ Advisors | BLACK PEARL 2020 |
| Alexion Services Europe; Biogen (Czech Republic) s.r.o.; BIOMARIN; Bristol-Myers Squibb (BMS); Chiesi Farmaceutici S.p.A.; CSL BEHRING; IPSEN PHARMA; | ECRD 2020 |
| Abeona Therapeutics; Aeglea Biotherapeutics; Agios Pharmaceuticals Inc.; Amgen (Europe) GmbH; Amicus Therapeutics UK Ltd; Argenx BVBA; Audentes Therapeutics, an Astellas company; Bayer AG; Bristol-Myers Squibb (BMS); Clinigen Group; Cydan II, Inc.; Gilead Sciences Belux; ICON Clinical Research S.A.R.L.; LEO Pharma A/S; LYSOGENE; Passage Bio; Sarepta Therapeutics; Takeda Pharmaceuticals International AG; UCB BioPharma SPRL; Vertex Pharmaceuticals; Zambon S.p.A. | ERTC RESTRICTED MEMBERSHIP 2020 |
| ACTELION - a Janssen pharmaceutical company of J&J; AKCEA THERAPEUTICS; Alexion Services Europe; Alira Health SAS; Alnylam Netherlands BV; Amryt Pharma; Avrobio; Biogen (Czech Republic) s.r.o.; BIOMARIN; BLUEBIRD BIO; Blueprint Medicines; BOEHRINGER | ERTC UNRESTRICTED MEMBERSHIP 2020 |
| AIPM (Association of International Pharmaceutical Manufacturers; Alexion Services Europe; Bristol-Myers Squibb (BMS); Chiesi Farmaceutici S.p.A.; Horizon Therapeutics; KYOWA KIRIN; NOVARTIS FARMA S.p.A.; PFIZER; PTC Therapeutics; Recordati Rare Diseases; Roche; SANOFI Genzyme; Takeda Pharmaceuticals International AG | EURORDIS INTERNATIONAL INITIATIVES 2020 |
| ACTELION - a Janssen pharmaceutical company of J&J; Amicus Therapeutics UK Ltd; Bristol-Myers Squibb (BMS); CSL BEHRING; Illumina Cambridge Ltd.; LEO Pharma A/S; Takeda Pharmaceuticals International AG | RARE BAROMETER 2020 |
| AUDENTES, BIOMARIN, BLUEBIRD BIO, CELGENE, CHIESI, NOVARTIS, ORCHARD THERAPEUTICS, PFIZER, PTC, REGENXBIO, SANGAMO, SANOFI GENZYME, SHIRE, SPARK THERAPEUTICS, ULTRAGENYX, VERTEX | RARE IMPACT 2020 - |

2.8 Close family member interest

No interest declared

2.9 Repurposing of a medicinal product

No interest declared

2.10 Any other interests or facts

*IRDiRC: International Rare Disease Research Consortium - Immediate past-Chair of Therapies Scientific Committee (until 2016) and past member of IRDiRC Therapies Scientific Committee (until 2018)-(www.irdirc.org)

*Co-chair of the Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease:
EURORDIS-Rare Diseases Europe, Microsoft and Shire (now Takeda) have formed the Global Commission to End the Diagnostic

Odyssey for Children with a Rare Disease, aiming to shorten the often multi-year journey that patients and families endure before being diagnosed with a rare disease.
The Global Commission is a multi-disciplinary group of experts with the creativity, technological expertise and commitment required to make a major difference in the lives of millions of children and their families. The Global Commission goal was to produce a roadmap for the rare disease field that focuses on solutions to core barriers preventing timely diagnosis for all rare diseases ? with an emphasis on those affecting children.
The Global Commission has published on February 20th 2019 a report with actionable recommendations. By focusing on children, the Global Commission can impact a large segment of the rare disease community and change the trajectory of children's lives. Additionally, the findings will have applications for all rare disease patients, and the medical field at large.
For the two companies, the Global Commission is a corporate social responsibility activity, with no link to any specific technology or product. There is no funding link between the two companies and EURORDIS for this Global Commission. More information https://www.globalrarediseasecommission.com/AboutUs

* In the context of the EU Pharmaceutical Strategy, the recent launch of the evaluation of the OMP & Paediatric Medicines EU regulation, and the persistent challenges in access, EURORDIS supports multi-stakeholders exchange to analyse the situation, elaborate new solutions and foster dialogue. Accordingly, I/EURORDIS has joined:
? The 'European Expert Group on Orphan Product Incentives'-started Q3/2020-supported by EUCOPE and several companies, this multi-stakeholder group has the objective to look specifically at the incentives framework in Europe. Expected duration until Q4/2021.
? The working group 'EFPIA/EURORDIS dialogue on Access to OMPs'-started Q4/2020. The intention of this structured dialogue is to identify alignment and opportunities to improve access for RD patients across Europe. The dialogue will not resolve in joint positioning. Expected duration until Q4/2021.

2.11 CAT member or alternate

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 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 clearly indicate that the views are my own if acting in my own capacity or those of the EMA, Committee, Working Party, Expert Group or other group if acting on behalf 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 to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website.

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|---|---|
| Full Name: | Yann LE CAM |
| Date: | 2020-12-22 |

*For Definitions of activities etc, refer to Policy on Handling of competing interests / Electronic DOI template*