



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, **Alessandro Aiuti**

Organisation/Company: SR-Tiget

Country: Italy

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

Period	Company	Products	Therapeutic Indication
11/2018-11/2018	Sanofi	Advice on gene therapy products	(one day activity)

2.3 Strategic advisory role

No interest declared

2.4 Financial interests

No interest declared

2.5 Principal investigator

Period	Company	Products	Therapeutic Indication
03/2013-12/2019	GSK/Orchard Therapeutics Limited (since April 2018)	Strimvelis	ADA-deficient SCID
01/2014-(current)	GSK/Orchard Therapeutics Limited (since April 2018)	Autologous CD34+ cells transduced with lentiviral vector encoding WAS cDNA	Wiskott Aldrich Syndrome

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		(OTL-103)	
03/2016-(current)	GSK/ Orchard Therapeutics Limited (since April 2018)	Autologous CD34+ cells transduced with lentiviral vector encoding ARSA cDNA (OTL-200)	Metachromatic Leukodystrophy
04/2015-07/2020	GSK/ Orchard Therapeutics Limited (since April 2018)	Autologous CD34+ cells transduced with lentiviral vector encoding beta-globin cDNA (OTL-300)	Transfusion dependent Beta-thalassemia
11/2017-(current)	GSK/ Orchard Therapeutics Limited (since April 2018)	Cryopreserved, autologous CD34+ cells transduced with lentiviral vector encoding ARSA cDNA (OTL-200)	Metachromatic Leukodystrophy
01/2019-(current)	Orchard Therapeutics Limited	Autologous CD34+ cells transduced with lentiviral vector encoding WAS cDNA, cryopreserved formulation (OTL-103)	Wiskott Aldrich Syndrome
05/2018-07/2020	Orchard Therapeutics Limited (since May 2019)	Autologous CD34+ cells genetically modified with IDUA lentiviral vector encoding for the human alfa-L-iduronidase gene (OTL-203)	Mucopolysaccharidosis Type I, Hurler variant

## 2.6 Investigator

Period	Company	Products	Therapeutic Indication
06/2018-12/2019	Wave Life Sciences	WVE-210201	Duchenne muscular dystrophy
10/2017-(current)	GSK/ Orchard Therapeutics (since April 2018)	Autologous CD34+ cells transduced with lentiviral vector encoding beta-globin (long-term follow up study) (OTL-300)	Transfusion dependent beta-thalassemia

## 2.7 Grant / Funding to organisation /institution

Company	Subject Matter
GSK/Orchard Therapeutics Limited	Fondazione Telethon and Ospedale San Raffaele are entitled to receive milestone payments and royalties from on licensed product according to contract.

## 2.8 Close family member interest

No interest declared

## 2.9 Repurposing of a medicinal product

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No interest declared

## 2.10 Any other interests or facts

- Coordinator and Unit PI of Italian Ministry of Health funded grant NET2011: "New strategies for gene therapy of primary immunodeficiencies using regulated lentiviral vectors and gene targeting approaches". 2015-2018.
- Coordinator of European Community grant FP. Advanced cell-based therapies for the treatment of primary immunodeficiencies (CELL-PID). 2010-2015
- Member of the Board of the Italian Working Group on Immunodeficiencies (IPINET) (2010-present).
- Board Member of ESGCT (2012 ? present).
- Chair of ASGCT Hematologic and Immunologic Gene and Cell Therapy Committee (2013-05/2016).
- Member of the Inborn Errors Working Party (IEWP) Studies Committee of the European Society for Bone and Marrow Transplantation (EBMT) (since 2015).
- Member of ASGCT Hematologic and Immunologic Gene and Cell Therapy Committee (since 2016).

## 2.11 CAT member or alternate

### 2.11.1 Employment

No interest declared

### 2.11.2 Consultancy

No interest declared

### 2.11.3 Strategic advisory role

No interest declared

### 2.11.4 Financial interest

No interest declared

### 2.11.5 Clinical investigator

No Interest Declared

### 2.11.6 Grant / Funding to organisation/institution

No interest declared

### 2.11.7 Close family member interest

No interest declared

### 2.11.8 Any other interests or facts

- Coordinator and Unit PI of Italian Ministry of Health funded grant NET2011: "New strategies for gene therapy of primary immunodeficiencies using regulated lentiviral vectors and gene targeting approaches". 2015-2018.
- Coordinator of European Community grant FP. Advanced cell-based therapies for the treatment of primary immunodeficiencies (CELL-PID). 2010-2015
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-Member of ASGCT Hematologic and Immunologic Gene and Cell Therapy Committee (since 2016).

## 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.

Full Name:	Alessandro Aiuti
Date:	2020-12-27

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