



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 |

|                   |  |   |  |
|-------------------|--|---|--|
|                   |  | (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-(current) | 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-(current) | Orchard Therapeutics Limited (since May 2019)        | Autologous CD34+ cells genetically modified with IDUA lentiviral vector encoding for the human alpha-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 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).

## 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.
- 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.

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.

|                   |                  |
|-------------------|------------------|
| <b>Full Name:</b> | Alessandro Aiuti |
| <b>Date:</b>      | 2019-12-23       |

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