

EUHA Symposium

European academia at the forefront of Advanced Therapies Medicinal Products development

13th November 2024
San Raffaele Conference Room

Agenda

9:30–9:40 **Opening**

- Anna Flavia d'Amelio Einaudi, CEO, Vita-Salute San Raffaele University, Research Director, San Raffaele Hospital and President, EUHA

9:40–9:50 **Institutional greetings**

- Francesco Saverio Mennini, Head of Department Planning, Medical Devices, Drugs and the National Health Service, Italian Ministry of Health
- Guido Bertolaso, Welfare Councilor, Lombardy Region
- AIFA (TBC)

SESSION I

Policy perspectives on ATMPs

Chair: Johan Van Eldere, Secretary-General, EUHA

10:00–10:20 **Challenges and opportunities for ATMP development: the regulatory perspective**

- Martina Schüßler-Lenz, Paul-Ehrlich Institute, German Federal Institute for Vaccines and Biomedicines, and Former Chair of the Committee for Advanced Therapies (CAT) of the European Medicines Agency's (EMA)

10:20–10:40 **The HTA evaluation of ATMPs: balancing accessibility and sustainability**

- Pier Paolo Olimpieri, Head of Unit, Italian Medicines Agency (AIFA)

10:40–11:00 **Coffee break**

11:00–11:20 **The EU Pharmaceutical Reform and its impact on ATMP**

- Paschalia Koufokotsiou, Policy officer – DG SANTE

11:20–11:40 **The industry perspective**

- Michela Gabaldo, VP Atmp global regulatory affairs, EVOTEC

11:40–12:00 **The non-profit perspective**

- Celeste Scotti, Head of Research and Development, Fondazione Telethon

12:00–12:20 **The learned society perspective**

- Juan Bueren, Head of Division, Centro Investigaciones Energéticas, Medioambientales y Tecnológicas (CIEMAT) and former President of the European Society of Gene & Cell Therapy (ESGCT)

12:20–13:30 **Networking lunch**

SESSION II

How to translate academic ATMP development into the regulatory context

Chair: Alessandro Aiuti, Professor, Vita-Salute San Raffaele University, Deputy director clinical research SR-Tiget San Raffaele Hospital and co-coordinator Join4ATMP project

13:30–14:30 **Roundtable**

- Alessandro Aiuti, Professor, Vita-Salute San Raffaele University and San Raffaele Hospital
- Paschalia Koufokotsiou, DG SANTE
- Michela Gabaldo, EVOTEC
- Martina Schüßler-Lenz, Paul-Ehrlich Institute

SESSION III

From ATMPs to other innovative approaches in medicine: an academic perspective

Chair: Chiara Bonini, Professor, Vita-Salute San Raffaele University and Research Group Leader San Raffaele Hospital

14:40–15:00 **ATMP manufacturing and patient treatment: the experience and perspective from academia**

- Reno Debets, Professor, Erasmus Medical Center

15:00–15:20 **International Standards for ATMPs medical and laboratory practice: current FACT and Jacie-EBMT guidance**

- Fabio Ciceri, Professor, Vita-Salute San Raffaele University and Director, Cancer Center San Raffaele Hospital

15:20–15:40 **The JOIN4ATMP project: mapping the hurdles and finding solutions for ATMP development**

- Annette Künkele-Langer, Professor, Charité and Join4ATMP Coordinator

CONCLUSION

15:40–16:00 **Milan Declaration on ATMPs and closing**

- Johan Van Eldere, Secretary General, EUHA
- Gianvito Martino, Scientific Director, San Raffaele Hospital and Vice-Rector Vita-Salute San Raffaele University



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