BRITISH SOCIETY OF TOXICOLOGICAL PATHOLOGY

The 38th Annual Scientific Meeting of the British Society of Toxicological Pathology



Preclinical translatability and pathology of cell-based therapies

Wednesday 15th – Thursday 16th November 2023 Evotec, Verona, Italy

Approved by the Royal Society of Biology for purposes of CPD, this event may be counted as 33 CPD credits. Approximately 11.5 hours of educational activity will be recorded on Attendance Certificates.

PROGRAMME

Wednesday 15th November 2023			
08.30 - 09.15	REGISTRATION		
09.15 - 09.30	WELCOME AND INTRODUCTION BY THE PRESIDENT OF THE BSTP - Catherine Ross		
Session 1: Advancing Cell-Based Therapies (Chair: Catherine Ross)			
09.30 - 10.15	Cell and gene therapy: Current advances and new perspectives for cell genetic engineering Prof Luigi Naldini (San Raffaele Telethon Institute for Gene Therapy, Italy)		
10.15 - 11.00	Designing safer gene transfer vectors and stem cell manufacturing processes Prof Fulvio Mavilio (Orchard Therapeutics, UK)		
11.00 - 11.30	REFRESHMENT BREAK AND POSTER SESSION		
Session 2: Cell-based Therapies: Therapeutic Opportunities I (Chair: Aleks Zalewska)			
11.30 - 12.15	Use of differentiated pluripotent stem cells as powerful and complex ATMP on the treatment of monogenic diseases Dr Ana Bejanariu (Sanofi, France)		
12.15 - 13.00	Harnessing the power of haematopoietic stem cells: From bench to bedside Prof Bernhard Genter (San Raffaele Telethon Institute for Gene T Therapy, Italy)		
13.00 - 13.15	Deciphex Sponsor Talk DECIPHEX		
13.15 - 14.15	LUNCH		
14.15 - 15.00	Neuronal stem cell transplantation in patients with progressive multiple sclerosis Prof Gianvito Martino (IRCCS San Raffaele Scientific Institute, Italy)		
	Session 3: Modifying Lymphocytes (Chair: Peter Clements)		
15.00 - 15.20	T2EVOLVE: A European initiative to speed up the availability of CAR-T therapy in Europe Dr Carmen Sanges (UKW, Germany)		
15.20 - 15.40	Profiling CAR-T cell performances in humanized mice Dr Monica Casucci (IRCCS San Raffaele Scientific Institute, Italy)		
15.40 - 16.00	Predicting safety and efficacy of engineered T cells using an ex vivo human model Dr Emmanuel Donnadieu (INSERM, France)		
16.00 - 16.30	REFRESHMENT BREAK		
16.30 - 17.00	Tregs: Opportunities & challenges Dr Jan Klapwijk (Cornelis Consulting, UK)		
17.00 - 17.30	Case studies: Challenges during preclinical assessment of 2 cell-based therapies Dr Deon Hildebrand (GSK, UK)		
17.30 onwards	Canapé Reception & transfer to city centre		

Registered Charity No: 1043793

BRITISH SOCIETY OF TOXICOLOGICAL PATHOLOGY

The 38th Annual Scientific Meeting of the British Society of Toxicological Pathology



Preclinical translatability and pathology of cell-based therapies

Wednesday 15th – Thursday 16th November 2023 Evotec, Verona, Italy

Approved by the Royal Society of Biology for purposes of CPD, this event may be counted as 33 CPD credits. Approximately 11.5 hours of educational activity will be recorded on Attendance Certificates.

PROGRAMME

08.15 - 08.55 REGISTRATION 08.15 - 09.00 INTRODUCTION TO DAY 2 BY THE PRESIDENT OF THE BSTP - Catherine Ross Session 4: Best Practices in Preclinical Development of Cell-based Therapy Products (Chair: Jan Klapwijk) 09.00 - 09.45 Products (Chair: Jan Klapwijk) ESTP Science Award 2023 Robe of pothology in regenerative solid organ cell therapy strategies Dr Magnus Söderberg (AstraZeneca, Sweden) 10.30 - 10.30 Products Dr Alys Bradley (Charles River Laboratories, UK) 10.30 - 11.00 REFRESHMENT BREAK AND POSTER SESSION 11.00 - 11.45 Products Dr Patrizia Cristofori (San Raffaele Telethon Institute for Gene Therapy, Italy) Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) 11.45 - 12.10 Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Lella Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner — an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy) 16.30 - 16.45 CONCLUDING REMARKS BY THE PRESIDENT OF THE BSTP – Catherine Ross				
Session 4: Best Practices in Preclinical Development of Cell-based Therapy Products (Chair: Jan Klapwijk)		Thursday 16th November 2023		
Session 4: Best Practices in Preclinical Development of Cell-based Therapy Products (Chair: Jan Klapwijk) 09.00 - 09.45 Role of pathology in regenerative solid organ cell therapy strategies Dr Magnus Söderberg (AstraZeneca, Sweden) 109.45 - 10.30 IATP Maronpot Guest Lecture Award Recipient The Pathologist's role in the Preclinical Strategy for Cell Based Medicinal Products Dr Alys Bradley (Charles River Laboratories, UK) 10.30 - 11.00 REFRESHMENT BREAK AND POSTER SESSION Patrizia Cristofori (San Raffaele Telethon Institute for Gene Therapy, Italy) Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) Preclinical strategy & challenges of iPSC-based cell therapeutics Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 Session 6: Regulatory Corner – an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	08.15 - 08.55	REGISTRATION		
Rose of pathology in regenerative solid organ cell therapy strategies Dr Magnus Söderberg (AstraZeneca, Sweden) O9.45 - 10.30 IATP Maronpot Guest Lecture Award Recipient The Pathologist's role in the Preclinical Strategy for Cell Based Medicinal Products Dr Alys Bradley (Charles River Laboratories, UK) 10.30 - 11.00 REFRESHMENT BREAK AND POSTER SESSION Pathology of graft-host interactions Dr Patrizia Cristofori (San Raffaele Telethon Institute for Gene Therapy, Italy) Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) Preclinical strategy & challenges of iPSC-based cell therapeutics Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner – an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Glo Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	08.55 - 09.00	INTRODUCTION TO DAY 2 BY THE PRESIDENT OF THE BSTP - Catherine Ross		
09.00 - 09.45 Role of pathology in regenerative solid organ cell therapy strategies Dr Magnus Söderberg (AstraZeneca, Sweden) 1ATP Maronpot Guest Lecture Award Recipient The Pathologist's role in the Preclinical Strategy for Cell Based Medicinal Products Dr Alys Bradley (Charles River Laboratories, UK) 10.30 - 11.00 REFRESHMENT BREAK AND POSTER SESSION 11.00 - 11.45 Pathology of graft-host interactions Dr Patrizia Cristofori (San Raffaele Telethon Institute for Gene Therapy, Italy) Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) Preclinical strategy & challenges of iPSC-based cell therapeutics Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	Session 4: Best Practices in Preclinical Development of Cell-based Therapy Products (Chair: Jan Klapwijk)			
The Pathologist's role in the Preclinical Strategy for Cell Based Medicinal Products Dr Alys Bradley (Charles River Laboratories, UK) 10.30 - 11.00 REFRESHMENT BREAK AND POSTER SESSION 11.00 - 11.45 Pathology of graft-host interactions Dr Patrizia Cristofori (San Raffaele Telethon Institute for Gene Therapy, Italy) Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) 11.45 - 12.10 Preclinical strategy & challenges of iPSC-based cell therapeutics Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner — an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 3.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	09.00 - 09.45	Role of pathology in regenerative solid organ cell therapy strategies		
11.00 - 11.45 Pathology of graft-host interactions Dr Patrizia Cristofori (San Raffaele Telethon Institute for Gene Therapy, Italy) Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) 11.45 - 12.10 Preclinical strategy & challenges of iPSC-based cell therapeutics Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner — an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 3.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	09.45 - 10.30	The Pathologist's role in the Preclinical Strategy for Cell Based Medicinal Products		
Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements) 11.45 - 12.10	10.30 - 11.00	REFRESHMENT BREAK AND POSTER SESSION		
11.45 - 12.10 Preclinical strategy & challenges of iPSC-based cell therapeutics Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner – an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 3.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	11.00 - 11.45			
Dr Matthias Austin (Evotec, Germany) Generating Preclinical Safety Data for a First-in-Class Regenerative Cell Therapy for Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner — an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 3.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	Session 5: Cell-based Therapies: Therapeutic Opportunities II (Chair: Peter Clements)			
Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization Dr Leila Abbas (RINRI Therapeutics, UK) Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner — an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 13.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	11.45 - 12.10	The state of the s		
Reliable Safety Testing for the Rapidly Growing Gene Therapy Cohort of Treatments is Becoming More Urgent Robert Spencer (TestAVec) 12.50 - 13.50 LUNCH Session 6: Regulatory Corner – an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 13.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	12.10 - 12.35	Hearing Loss: A collaboration between Academia, Biotech and a Contract Research Organization		
Session 6: Regulatory Corner – an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori) 13.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	12.35 - 12.50	Treatments is Becoming More Urgent		
13.50 - 14.50 Scientific advice from MHRA - an example - Project X Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	12.50 - 13.50	LUNCH		
Dr James McBlane (MHRA, UK) Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini) Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	Session 6: Regulatory Corner – an interactive case with the MHRA (Chair: Jan Klapwijk and Patrizia Cristofori)			
Challenges and opportunities in preclinical development of combined cell-based medical device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	13.50 - 14.50			
14.50 - 15.35 device products Dr Pramila Singh (Charles River Laboratories, UK) 15.35 - 16.05 REFRESHMENT BREAK AND POSTER SESSION Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	Session	Session 7: Combined Medical Device & Cell-based Therapies (Chair: Gio Pellegrini)		
16.05 - 16.30 Cell therapy combined with a medical device to treat type 1 diabetes Dr Michela Gabaldo (Evotec, Italy)	14.50 - 15.35	device products		
16.05 - 16.30 Dr Michela Gabaldo (Evotec, Italy)	15.35 - 16.05	REFRESHMENT BREAK AND POSTER SESSION		
16.30 - 16.45 CONCLUDING REMARKS BY THE PRESIDENT OF THE BSTP – Catherine Ross	16.05 - 16.30	''		
	16.30 - 16.45	CONCLUDING REMARKS BY THE PRESIDENT OF THE BSTP – Catherine Ross		

V: 08/11/2023

You are advised that the programme timings, lecture title and speakers may be subject to change without notice

Registered Charity No: 1043793

BRITISH SOCIETY OF TOXICOLOGICAL PATHOLOGY

The 38th Annual Scientific Meeting of the British Society of Toxicological Pathology



Preclinical translatability and pathology of cell-based therapies

Wednesday 15th – Thursday 16th November 2023 Evotec, Verona, Italy

Approved by the Royal Society of Biology for purposes of CPD, this event may be counted as 33 CPD credits. Approximately 11.5 hours of educational activity will be recorded on Attendance Certificates.

PROGRAMME

Registered Charity No: 1043793