14 November 2016
EMA/481413/2016
Inspections, Human Medicines Pharmacovigilance and Committees

Workshop on scientific and regulatory challenges of genetically modified cell-based cancer immunotherapy products

Programme

Date: 15 – 16 November 2016, meeting room 03-A

Location: European Medicines Agency, London, E14 5EU, UK

Workshop Chair: Paula Salmikangas, CAT Chair, FIMEA

Day 1

07:45 Registration

08:30 Welcome and introductions

▪ Welcome address	Guido Rasi, EMA	8.30 – 8.40
▪ Introduction and regulatory update	Paula Salmikangas, FIMEA	8.40 – 8.55
▪ EU Support to ATMP developers	Patrick Celis, EMA	8.55 – 9.10

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09:10 Session 1: Overview of T-cell therapies – current status

Session Chairs: Paula Salmikangas, FIMEA and Marit Hystad, NOMA

▪ Chimeric antigen receptor (CAR) T-cells	David Lebwohl, Novartis Pharmaceuticals	9.10 – 9.40
▪ Overview on T-cell therapies: current status	Bruce Levine, University of Pennsylvania	9.40 – 10.10
▪ Natural killer (NK) cells	Evren Alici, Karolinska University Hospital	10.10 – 10.40

10:40 Coffee Break

11:00 Session 2: Next generation T-cells

Session Chairs: Bernd Gänsbacher, Technical University of Munich and Rune Kjeken, NOMA

▪ Off-the-shelf CARs	Julianne Smith, Cellectis	11.00– 11.25
▪ CARs and TRUCKs: how engineered T-cells become living factories	Hinrich Abken, University of Cologne	11.25 – 11.50
▪ A universal approach to T-cell therapies	Michael Vasconcelles, Unum Therapeutics	11.50 – 12.15
▪ Open discussion: current and future development of the field		12.15 – 13.00

13:00 Light Lunch

14:00 Session 3: Product manufacturing and testing

Session Chairs: Christiane Niederlaender, MHRA and Paula Salmikangas, FIMEA

▪ Manufacturing challenges - now and how will we ensure patient access to these medicines	Bo Kara, GlaxoSmithKline	14.00 – 14.30
▪ Production and validation of CAR T-cells and T-cell receptors (TCRs) in academic setting	Martin Hildebrandt, Technical University of Munich	14.30 – 15.00
▪ Quality development considerations – regulatory perspective	Christiane Niederlaender, MHRA	15.00 – 15.20
▪ Open discussion on quality challenges		15.20 – 16.00

16:00 Coffee

16:30 Session 4: Non-clinical development

Session Chairs: Björn Carlsson, MPA; Metoda Lipnik-Stangelj, University of Ljubljana and Dariusz Sladowski, University of Warsaw

▪ Biomarkers of response for translational research	Margo Roberts, Kite Pharma	16.30 – 17.00
▪ Preclinical safety testing of enhanced-affinity TCRs for adoptive T-cell therapy	Andrew Gerry, Adaptimmune	17.00 – 17.30
▪ Beyond HER2 CAR T-cells: consider how far you have fallen…	Nabil Ahmed, Baylor College of Medicines	17.30 – 18.00
▪ Challenges in the non-clinical development of CARs and TCRs	Björn Carlsson, MPA	18.00 – 18.20
▪ Open discussion on non-clinical challenges		18.20 – 19.00

19:00 End of Day 1

Day 2

09:00 Session 5: Clinical challenges and experience

Session Chairs: Martina Schüßler-Lenz, PEI and Olli Tenhunen, FIMEA

▪ Clinical and regulatory challenges in the development of CAR-modified and TCR-modified T-cells in the EU	Martina Schüßler-Lenz, PEI	9.00 – 9.20
▪ Experience from scientific advices for CARs/TCRs	Olli Tenhunen, FIMEA	9.20 – 9.40
▪ FDA pilot project to develop a clinical database to examine safety in trials using CAR T-cells	Maura O'Leary, FDA/CBER	9.40 – 10.10
▪ Challenges related to the translation of TCRs to the clinic – the view of an academic developer	Gerald Willimsky, Charité, University Berlin	10.10 – 10.40
▪ Taking CARs/TCRs from first-in-man trials to marketing authorisation – the view from a pharmaceutical developer	Stanley Frankel, Celgene Corporation	10.40 – 11.10

11:10 Coffee

11:30 Continues from Session 5

▪ Open discussion on clinical development	11.30 – 12.15

12:15 Conclusions and closure of the workshop

▪ Regulatory / scientific challenges and conclusions	Session Chairs	12.15 – 12.55
▪ Close of the workshop	Paula Salmikangas, FIMEA	12.55 – 13.00

13:00 End of the workshop