REGULATORY WORKSHOP ON THE DEVELOPMENT OF CAR-T CELLS

Jointly organized by the H2020 projects

EURE-CART (European Endeavour for Chimeric Antigen Receptor Therapies) **&**

CARAMBA (SLAMF7-CAR T for Immunotherapy of Multiple Myeloma)

Sitges (Spain), January 29-30, 2020;

Venue: Melia Sitges Hotel

PROGRAMME

Wednesday, January 29, 2020

13:00-13:45	Arrival and registration Welcome coffee	*All*
13:45-14:00	Welcome and introduction: scope and objectives of the Regulatory Workshop	*M.C. Galli /* *M. Hudecek*
Session 1 (closed): Update on EURE-CART and CARAMBA (chair: M.C. Galli, D. Alberti)		
14:00-14:20	Overview of EURE-CART	*C. Traversari*
14:20-14:40	Overview of CARAMBA	*M. Hudecek*
14:40-15:10	Regulatory issues in EURE-CART: experiences of an SME	*D. Alberti*
15:10-15:40	Regulatory issues in CARAMBA: experiences of an academic hospital	*M. Hudecek*
15:40-16:10	Q&A	*all*
16:10-16:30	Coffee break	
Session 2 (closed): Issues emerged from project experience (chair: F. Moretti, M. Hudecek)		
16:30-16:50	Requirements for CAR T cells to enter first-in-human studies: view from assessors	*M. C. Galli*
16:50-17:10	Requirements for CAR T cells to enter first-in-human studies: view from a consultant in regulatory affairs	*R. Doblhofer*
17:00-17:45	Round table: Requirements for CAR T cells to enter first-in-human studies (quality assurance, non-clinical data): case reports and experiences in other EU countries	*A. Ståhlbom* *M. Timón* *Y. Zhao*
17:45-18:15	Q&A	*all*
18:15-18:30	Wrap-up	*C.Traversari* *M.Hudecek*

These projects have received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733297 and 754658.

REGULATORY WORKSHOP ON THE DEVELOPMENT OF CAR-T CELLS

Jointly organized by the H2020 projects

EURE-CART (European Endeavour for Chimeric Antigen Receptor Therapies) **&**

CARAMBA (SLAMF7-CAR T for Immunotherapy of Multiple Myeloma)

Sitges (Spain), January 30, 2020;

Venue: Melia Sitges Hotel

PROGRAMME

Thursday, January 30, 2020

08:00-08:30	Arrival and registration	*All*
Open Session: CAR T first-in-human clinical trials - where we are and future perspectives (chair: Z. Ivics, C. Traversari)		
08:30-08:45	Overview on CAR T development and regulatory aspects in EURE-CART and CARAMBA	*M.C. Galli*
08:45-09:15	Requirements to enter first-in-human studies: manufacturing, quality assurance, non-clinical data	*M. Schüssler-Lenz*
09:15-09:35	Harmonization efforts on GMO issues for clinical trials with gene therapy products	*M. Timón*
09:35-09:50	Coffee break	
09:50-10:10	Requirements for CAR T cells to enter first-in-human studies: view from a consultant in regulatory affairs	*R. Doblhofer*
10:10-10:30	Views from EATRIS – the European Infrastructure for Translational Medicine	*F. Bietrix*
10:30-11:30	Round table: Harmonisation of first-in-human studies review in the EU ✓ Past, Present and Future ✓ Experiences in academy, SMEs and industry	*Chair: M. Schüssler-Lenz* *M. Hudecek, H. Bönig* *M. C. Galli, D. Alberti* *A. Ståhlbom, M. Timón* *Y. Zhao* *R. Doblhofer*
11:30	Conclusion remarks Bagged lunch	*M.C. Galli* *M. Hudecek*

These projects have received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733297 and 754658.