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.