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GoCART COALITION

GoCART Coalition has continued to work actively in 2022 bringing partners together to discuss issues on the complex field of cellular therapies. GoCART Coalition, joint collaboration by EBMT and EHA, aims to promote patient access to novel cellular therapies and to contribute to health and well-being by multi-stakeholder collaboration on clinical data, standards of care, education and policy. GoCART's vision is to create a platform driven by input from a diverse group of stakeholders who jointly develop projects that advance the field of cellular therapies in Europe.

Main achievements of 2022

Work package 1: Data Harmonisation

The Data Harmonisation Work Package carried out a number of multi-stakeholder meetings and a revision of the EBMT Cellular Therapies data collection form between 2020-2022. Final draft was presented to stakeholders in March 2022. First key elements have been implemented in 2022 in the forms used for the new EBMT Registry update. Additional, yet not implemented fields, will become part of the annual renewal process of updating forms. The process of upcoming changes will be discussed with all stakeholders and implemented in 2023/4.

Work package 2: Standards of Care

Work Package 2 worked on a number of projects in 2022.The GoCART Coalition announced on 8th March 2022 a new initiative to allow apheresis and cell therapy treatment centres accredited by JACIE to leverage their accreditation as part of site qualification processes for Bristol Myers Squibb, Janssen, Kite and Novartis. Subject to marketing authorisation holders' agreement and obligations, centres holding JACIE accreditation have the option of undergoing a reduced or remote audit focused on product-specific requirements for cell therapies. Subject to marketing authorisation holders' agreement and obligations, centres holding JACIE accreditation will have the option of undergoing a reduced or remote audit focused on product-specific requirements for cell therapies.

The ongoing work with BMS, Janssen, Kite and Novartis includes specifying what this leverage means at a company level and working with other cell and gene therapy companies to join in leveraging JACIE accreditation.

GoCART Coalition Pharmacist Working Group developed a practical guidance on implementation and safe operational use of marketed CAR-T cell products within hospital pharmacies primarily throughout Europe. The guideline outlines the key areas where pharmaceutical expertise should focus on as well as key considerations for the hospital pharmacies. A manuscript has been accepted for publication and is expected to be published early 2023.

GoCART Coalition Apheresis Working Group has met a number of times to discuss ‘best practice’ in apheresis for optimal starting materials. These discussions have been captured in two manuscripts in process with plans to submit for publications in quarter one of 2023. The first manuscript will focus on pragmatic aspects of

apheresis in order to optimise the collection including venous access and apheresis platforms and technical aspects of the procedure.

A second manuscript will describe washout phases and manufacturing failures; sampling of the apheresis product and labelling and cryopreservation as well as provide an outlook.

Work package 3: HTA

EUnetHTA, the European Network for Health Technology Assessment, has given input in the revision of the EBMT Cellular Therapy form within WP1 on Data Harmonisation.

Work package 4: Education

GoCART continued with the two established series of educational webinars that take place every month. In the Clinical Case Discussion series for physicians two cases are presented and discussed with experts in the field of CAR T-cell therapies. The aim is to discuss real-life clinical cases as instructive examples, foster lateral thinking to meeting participant’s own cases, and contribute to a broader understanding of CAR T-cell treatments, toxicity management and outcomes. Ten sessions and twenty clinical cases were discussed in 2022.

The Nurses Best Practice Sharing Sessions focus on different aspects of the patient journey and/or the care nurses provide. In the meetings a nurse expert will present the theoretical background information and present a real-life case. In 2022 the group hosted six Best Practice Sharing Sessions.

Plans for the future work include exploring harmonisation of training requirements with GoCART Industry partners.

Work Package 5: Policy and Advocacy

GoCART continued to contribute to the response by its founding organisations to the draft proposal by the European Commission on the Revision of the EU legislation on Blood, Tissues and Cells. Key areas identified were the introduction of the joint regulation approach promoting harmonisation across the Member States as well as the principles of voluntary unpaid donations and donor protection measures.

Further plans include developing a shared policy and advocacy strategy to advocate key coalition positions with the policy makers in order to contribute to European policy making on gene and cellular therapy topics including SoHO regulation and Hospital Exemption.

Work Package 6: Scientific Excellence

Second call of retrospective research proposals was released in Sept 2022. Total of sixteen scientific projects were submitted. Of these following a feasibility study on six proposals, three projects were selected by a Selection Committee including Prof Anna Sureda (President of the EBMT), Dr. Annalisa Ruggeri (Chair EBMT Cellular Therapies and Immunobiology Working Party), Prof. John Gribben (Past President of the EBMT), Prof. Martin Dreyling (Board member of EHA) and Natacha Bolanos (Chair EBMT patient advocacy committee The three winning proposals are listed below and will be supported by a dedicated GoCART Study team based at the EBMT.

1. **“Impact of preceding therapy on the feasibility, safety and efficacy of anti-CD19 CAR-T cells in acute lymphoblastic leukemia**”
   (co-PIs: Valentín Ortiz-Maldonado, Hospital Clínic, Barcelona, Spain and Sebastian Giebel, Maria Sklodowska-Curie National Research Institute of Oncology, Gliwice Branch, Poland),
2. **“Efficacy and toxicity of CAR T cell therapy in patients with primary and secondary central nervous system lymphoma. A Retrospective Analysis of the Lymphoma WP of the EBMT”**
   (PI: Anna Laube, Helios Klinikum Berlin, Germany)
3. **“Infections following CAR-T therapy. A retrospective collaborative study between the IDWP, CTIWP, TCWP of the EBMT, the European Hematology Association (EHA), and the Medical College of Wisconsin”**
   (PI: Dina Averbuch, Hadassah University Hospital, Jerusalem, Israel).

GoCART also published a first newsletter of the Coalition in December 2022. You can join the mailing list for this bi-monthly newsletter on thegocartcoalition.com

If you want to get involved in the GoCART activities and work with different stakeholders to maximise the potential of cellular therapies, please visit thegocartcoalition.com website or send an e-mail to GoCART@ebmt.org

Visit the GoCART coalition website