Therakos™
ECP Immunomodulation

50th EBMT HIGHLIGHTS

Celebrating 30 years of ECP for GvHD patients

50th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT)

14–17 April 2024 – Scottish Event Campus, Glasgow, UK

30 years of ECP for GvHD patients

The Annual Meeting of the EBMT is Europe's largest congress devoted to exploring the latest advances in blood and marrow transplantation and cellular therapies that aim to transform patient outcomes.

This annual event promotes connection, education and information exchange across a global community representing a wide network of disciplines involved in scientific research in transplant and cellular therapies and delivery of care, including physicians, nurses, data managers, statisticians, cell therapists, paediatricians, psychiatrists and transplant coordinators, lab scientists, and most importantly patients themselves.

Attracting delegates from all over the world, the 2024 event was a particularly special occasion, being a celebration of 50 years of EBMT Annual Meetings and an opportunity to look back at the remarkable progress the international transplant community has made over this time as well as looking forward to exciting opportunities on the horizon.

For Therakos, 2024 also marks 30 years since data on immunomodulatory therapy with extracorporeal photopheresis (ECP) was first published for the management of patients with chronic graft-versus-host disease (GvHD) who have become steroid-refractory or steroid-dependent, providing patients and clinicians with a potential future second-line treatment option in this challenging condition.[1]

Read some of the 50th EBMT **highlights**

- GvHD Hub – Celebrating 30 years of ECP for GvHD patients: Recommendations for the treatment of chronic GvHD
- Nurse symposium: Patient-centred therapy using THERAKOS ECP Immunomodulation™ technology, then, now and in the future
- THERAKOS ECP Immunomodulation™ – supporting physicians, patients and caregivers
- Developments in ECP immunomodulation – research highlights
- Optimising GvHD patient care – looking to the future
- 50 years of EBMT – a journey of innovation and hope

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Celebrating 30 years of ECP in GvHD management

Recommendations for the treatment of cGvHD

GvHDHub is an open-access online resource that provides evidence-based medical education in GvHD. In recognition of a milestone in the management of this challenging condition – 30 years of ECP therapy – the GvHD Hub hosted a special symposium at EBMT 2024.

Chaired by Professor Mohamed Mohty (France) the international faculty discussed the urgent need to address the long-term burden of chronic GvHD (cGvHD) in allogeneic hematopoietic stem cell transplant (allo-HCT) recipients, particularly as first-line corticosteroid therapy is generally only effective in around 50% of patients.[2] Although prophylactic therapies, such as post-transplant cyclophosphamide, have contributed to reducing the overall incidence of cGvHD, it is still a serious and common complication post-allo-HCT.

Studies have demonstrated that ECP and, more recently, ECP-based combination therapies are emerging as valuable second-line strategies in the setting of steroid-refractory (SR), -intolerant or -dependent cGvHD where there is an ongoing unmet need for increasingly effective treatments.

The long-term burden of cGvHD

Dr Bipin Savani (USA) presented the results of an analysis by the Chronic GvHD Consortium which found that non-relapse mortality in allo-HCT recipients diagnosed with cGvHD increases over time without any apparent plateau. Notably, the most common reported primary causes of death in this population are cGvHD and infection.[3]

A larger proportion of older adults are now receiving allo-HCT and their ability to tolerate corticosteroid therapy for cGvHD is often limited, so alternative treatment approaches are needed.

***L-R:** Dr Florent Malard, Dr Bipin Savani, Dr Zinaida Peric.*

Added to the challenge of living with and managing the chronic, debilitating physical symptoms of cGvHD, it can also have a considerable negative impact on the patient's quality of life, psychosocial wellbeing and, in many cases, be a financial burden due to physical limitations that affect the ability to work. Long-term follow-up clinics are therefore essential to the ongoing support of GvHD patients. Dr Savani stressed that these do not have to be large and complex programs and should be achievable with good staff training.

ECP-based combination therapies

Dr Florent Malard (France) described how the limitations of first-line corticosteroid therapy for cGvHD highlight the need for improved therapeutic approaches that can achieve good response rates while minimizing the need for long-term immunosuppression.

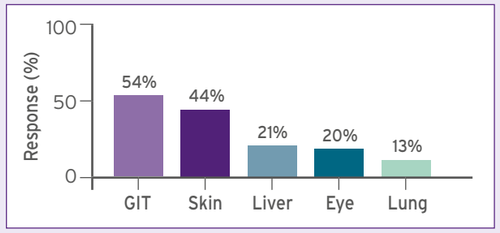

***Figure 1.** Response rates to ruxolitinib + ECP combination therapy according to GvHD affected organ. GIT, gastrointestinal tract.[6]*

Although the mechanism of action of ECP remains to be fully elucidated, it is known to have both direct and indirect immunomodulatory effects and importantly does not cause generalised immunosuppression.[4] In the treatment of cGvHD, ECP plus standard therapy has been shown in a prospective, Phase II, multicentre, randomized study to possibly have a beneficial steroid-sparing effect.[5]

Approval of several novel agents for the management of SR cGvHD in recent years, namely ibrutinib, belumosudil and ruxolitinib (RUX), has expanded the range of available second-line treatment options and promoted research into various combination strategies.

While allo-HCT is safer than ever before, cGvHD is still common, with estimates of around 50% of long-term survivors living with the condition.

A retrospective study of a combination of ECP and RUX was undertaken in 23 patients with SR-cGvHD to evaluate its efficacy and potential therapeutic synergy of the two compounds.[6] A complete response was achieved in 9% of subjects and a partial response in 65%, with the best responses seen in gastrointestinal tract and skin cGvHD (Figure 1). Of the patients who responded to ECP–RUX, 76% were able to taper their steroid dose and the overall survival at two years was 75%.

Clinical practice insights for optimizing ECP treatment

Dr Zinaida Peric (Croatia) presented an interactive discussion of real patient cases in which she highlighted key clinical practice points when considering ECP therapies.

Currently, there are no guidelines for the optimum ECP treatment schedule. Dr Peric considered that ECP every second week was a logical approach.

She noted that ECP had a useful role in combination with immunosuppressive agents in SR-cGvHD, particularly in high-risk patients ~ having the added benefit of a favourable safety profile.

Nurse Symposium: 30 years of ECP in GvHD

Nurses play an essential role in the implementation of ECP and in supporting patients through their GvHD treatment journey. A Therakos-sponsored symposium, chaired by Michelle Kenyon, President of the EBMT Nurses Group, explored the unique role that nurses have played in delivering patient-centred GvHD care with THERAKOS ECP Immunomodulation™ over the past 30 years.

Taking a holistic view of a GvHD patient's journey

To set the context for the importance of patient-centred care, Dr Francesca Kinsella, Director of the Birmingham Centre for Cellular Therapy and Transplantation in the UK, outlined the significant impact that cGvHD has on patients' wellbeing.

Quality of life in patients with cGvHD is known to be poor with impairments observed in physical, societal, psychological and sexual domains (Figure 2).[7]

Treatment of cGvHD can also be a significant burden to patients. The ultimate aim of cGvHD

Figure 2. *Impact of cGvHD on quality of life domains.*[7]

Figure 3. *The aim of GvHD treatment.*

treatment is to decrease alloreactivity over time and develop sustained clinical tolerance (Figure 3). However, many patients require multiple lines of treatment, may not achieve tolerance, or may fluctuate (flare) repeatedly as they cycle through different treatments.

A nurse operator's perspective on THERAKOS ECP Immunomodulation™

Laura Dalling, a nurse at Nottingham City Hospital in the UK, discussed her experience in delivering THERAKOS ECP Immunomodulation™ within the Apheresis Team. They currently have three THERAKOS™ CELLEX™ Photopheresis Systems which are used to treat both acute and chronic GvHD.

Due to an increasing demand for the service, they plan to expand capacity, and this will include education for the allo-HCT ward nurses and clinicians about the importance of ECP and the need to monitor blood results in a timely manner to ensure they are in range and the procedure can go ahead as planned. As there is often a long wait for Hickman lines, they also plan to implement ultrasound guided cannulation.

Patients report very positive experiences with the ECP service at Nottingham (Figure 4), in particular the personal interaction this allows with the healthcare team and other patients.

Figure 4. *Patient view of the ECP service, based on the presenter's experience.*

Patients are at the heart of the excellent clinical care that THERAKOS ECP Immunomodulation™ aims to deliver.

The Therakos exhibition booth showcased real patient stories from Anna, Robert, Wilfred and Elaine. They provide unique perspectives on their individual, physical and emotional battles through their disease, stem cell transplantation, living with GvHD, and their ECP treatment journey.

allo-HCT*, allogeneic haematopoietic stem cell transplantation;* ***aGvHD****, acute graft-versus-host disease;* ***cGvHD****, aGvHD, chronic graft-versus-host disease;* ***ECP****, extracorporeal photopheresis.*

THERAKOS ECP Immunomodulation™ – ongoing support for physicians, patients and caregivers

Delegates visiting the Therakos exhibition booth at EBMT 2024 were able to get a hands-on demonstration of the features of the latest THERAKOS™ CELLEX™ Photopheresis System.

They could also learn about the clinical benefits of ECP in cGvHD and the information and support available to healthcare teams, patients and caregivers.

Access to education and support

Therakos aims to provide comprehensive information and support to healthcare teams delivering care, to patients undergoing treatment, and to their caregivers. Patients and caregivers can access information about THERAKOS ECP Immunomodulation™ treatment at: ***https://therakos.eu/patients-and-caregivers/.***

Therakos INSTITUTE™
ECP Immunomodulation

The Therakos Institute provides accessible education to healthcare professionals with the aim of advancing knowledge and understanding of ECP immunomodulation. It hosts webinars, symposia, courses, and other educational sessions with leading experts from around the world: ***https://therakos.eu/therakos-institute/.***

Technological advancements over three decades

In 2024 Therakos is proudly celebrating three decades of THERAKOS ECP Immunomodulation™ for GvHD patients.

In 1987 THERAKOS™ UVAR was the **world's first photopheresis system.**

In the intervening decades Therakos has continued to advance providing state-of-the-art technology to meet the needs of patients and healthcare teams.

The latest THERAKOS™ CELLEX™ PLUS Photopheresis System is the **world's only** fully integrated and validated ECP system.

Developments in ECP immunomodulation – research highlights

Poster B044

Iryna Lastovytska, et al.
University Medical Centre Hamburg-Eppendorf, Germany

Improved long-term outcome of ruxolitinib plus ECP versus ruxolitinib alone in steroid-refractory acute GvHD

Although ruxolitinib (RUX) is approved for the treatment of steroid-refractory (SR)-aGvHD, there is still an unmet clinical need for better clinical responses and improved outcomes in aGvHD patients.

Encouraging outcomes have previously been reported in patients with SR-aGvHD treated with a combination of RUX and ECP.[8] The single-centre study in 18 patients found complete responses in 44% of patients and partial response in 11%, resulting in an estimated 2-year overall survival of 56%.

A retrospective study reported at EBMT 2024 by the same research team compared efficacy and outcomes between RUX alone versus RUX plus ECP combination therapy in 78 SR-aGvHD patients. The results of their analysis are shown in Table 1. After 12 months of treatment, the cumulative incidence of cGvHD was significantly higher in the group treated with RUX alone compared with the RUX–ECP-treated group: 51% versus 25% (p=0.01).

Non-relapse mortality and overall survival were not found to be significantly different between treatment groups at 12 months.

Table 1. *Results of the analysis.*

Timepoint	RUX + ECP (n=49)	RUX alone (n=29)
Day 28	ORR: 42 (86%); p<0.001 CR: 0 PR: 42 (86%)	ORR: 26 (89.6%); p<0.001 CR: 9 (31%) PR: 17 (58.6%)
6 months	n=28 ORR: 17 (61%); p<0.003 CR: 14 (50%) PR: 3 (11%)	n=20 ORR: 10 (50%); p<0.003 CR: 8 (40%) PR: 2 (9.5%)
12 months	n=25 ORR: 18 (72%); p<0.006 CR: 16 (64%) PR: 2 (8%)	n=18 ORR: 4 (22%); p<0.006 CR: 3 (16.6%) PR: 1 (5.5%)

ORR, overall response rate; CR, complete response; PR, partial response.

The authors concluded that RUX plus ECP in SR-aGvHD patients resulted in a better GvHD control after 12 months than RUX alone.

As this is a retrospective, single-centre study, further larger, prospective studies are needed to confirm these findings, along with validation in a peer-reviewed publication.

aGvHD*, acute graft-versus-host disease;* ***cGvHD****, aGvHD, chronic graft-versus-host disease;* ***ECP****, extracorporeal photopheresis.*

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Developments in ECP immunomodulation – research highlights (CONT.)

Poster P105

Khalid Halahleh, et al.
King Hussein Cancer Centre, Amman, Jordan

The efficacy and safety of ECP in steroid-dependent and -refractory GvHD: a cohort study from a comprehensive adult bone marrow transplantation program in Jordan

Table 2. *Results of the analysis.*

Parameter	aGvHD (n=19)	cGvHD (n-23)
Overall response rate	33% (10 CR, 4 PR)	43% (11 CR, 7 PR)
3-year overall survival Gut GvHD versus other sites	49% 83% versus 40%, p=0.028	70% (p=0.0001 versus no cGvHD)
Steroid dose	Steroid dose could be reduced by 50% in 19 patients (45%) and discontinued in 36 (86%) at a median of 95 days (range: 15-461 days).	

CR, complete response, PR, partial response.

This study was a retrospective analysis of the medical records of patients who received ECP for acute or chronic GvHD over a 10-year period (2013–2023).

A total of 42 patients were included in the analysis, 19 with Grade II–IV aGvHD and 23 with moderate-to-severe cGvHD. Efficacy results are shown in Table 2 and no major adverse events related to ECP treatment were reported.

The authors concluded that ECP was well-tolerated and an effective treatment for both aGvHD and cGvHD, and suggested it could be introduced early in the course of GvHD treatment.

As this is a retrospective, single-centre study, further larger, prospective studies are needed to confirm these findings, along with validation in a peer-reviewed publication.

aGvHD*, acute graft-versus-host disease;* ***cGvHD****, aGvHD, chronic graft-versus-host disease;* ***ECP****, extracorporeal photopheresis.*

Optimising GvHD patient care – looking to the future

Poster NP001

Debbie Andersen,
Bart's Health NHS Trust,
London, UK.

Setting up a GvHD patient support group

Nurse Debbie Andersen (UK) described how the idea for setting up a GvHD patient support group had come from patients themselves who attended St Bartholomew's Hospital for GvHD treatment. Evidence suggests this group is currently unique in the UK and the only one for patients specifically with GvHD, who face challenges that differ from those of other haemato-oncology patients.

The initiative is supported by Anthony Nolan and holds bimonthly meetings on Microsoft Teams. These start with an invited speaker talking about a GvHD related topic, followed by a group discussion. Topics covered in the group have included: the psychological impacts of GvHD, emerging treatments and latest research, ECP treatment, and cancer-related fatigue.

Patient feedback has been overwhelmingly positive and they have found the opportunity to discuss GvHD and the implications this has on their day-to-day lives invaluable.

Plenary Session

GvHD – State of the Art

Biology-driven treatment approaches for acute GvHD

Professor Robert Zeiser (Germany) discussed how acute GvHD (aGvHD), in particular the challenging manifestation of gastrointestinal (GI) aGvHD, had a negative impact on patient survival with high mortality rates being reported[9]. Finding timely and effective treatments is therefore critical. If standard first-line corticosteroid therapy fails, alternative second-line options need to be implemented. Professor Zeiser reviewed the available therapies that have been evaluated for their ability to target specific aspects of the underlying biology of GvHD, rather than providing generalised immunosuppression.

The REACH 1 and 2 studies of patients with SR-aGvHD have reported positive outcomes following 28 days of treatment with the selective Janus kinase (JAK) 1/2 inhibitor, ruxolitinib, although they observed a higher incidence of thrombocytopenia, the most frequent adverse effect, than with standard therapy.[10,11]

Professor Zeiser considered that in the setting of aGvHD, ECP immunomodulation was also a logical treatment option. It was superior to therapies that caused generalised immunosuppression as it induced tissue-specific immunosuppression. Reinfusion of apoptotic ECP-treated cells is known to result in their phagocytosis and the production of tolerogenic macrophages as well as secretion of anti-inflammatory cytokines and chemokines, and other beneficial immunomodulatory changes.[12]

ECP immunomodulation induces tissue-specific rather than generalized immunosuppression.

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Patient unmet needs in GvHD management and care

Educational Session

GvHD – Improving outcomes

Dr Helene Schoemans (Belgium) explored patients unmet need from a different perspective, posing the question: " Do we need to listen to GvHD patients and, if so, why?".

Listening to patients

We know that GvHD can have a huge negative impact on patients' quality of life (QoL), however the change in QoL is often underestimated by clinicians, highlighting the need to ask patients directly.[13] Following allo-HCT, patients report that while feeling 'cured' (of their disease), they still felt 'sick' (due to GvHD).

While there are a wide range of validated patients-reported outcome (PRO) tools used in GvHD, the specific needs of patients are not always captured by clinical trials and by using PROs, so they do not reveal the true picture. Better information can often be obtained by using Focus Groups and in-depth interviews.[14]

"This GvHD determines my life. That's it. To some extent I have lost hope that I will ever be able to reduce all this medication."

Female survivor, 57 years,
2.5 years post allo-HCT.

The cGvHD Eurograft initiative

A European initiative is now underway to better address unmet needs in GvHD patients. Eurograft ***(https://www.gvhd.eu/)*** is a cross-disciplinary network of European cGvHD experts that provides resources to support clinical teams, industry partners, patients and public groups.

By linking these stakeholders, Eurograft aims to improve patient care through harmonisation of the treatment approaches across transplant centres, and by strengthening research and innovation.

Development of a GvHD Community Advisory Board

One of the initiatives undertaken within the Eurograft Consortium was to develop a Community Advisory Board (CAB), a group of patients who offer their expertise to researchers.[15] The CAB comprised GvHD healthcare professionals from the Eurograft Network and two US-based GvHD patient advocates. Their aim was to understand the GvHD patients' unmet needs in terms of care and management and to co-create proposals for actionable targets to address them.

1. INFORMATION
2. EMPOWERMENT
3. DEDICATED CARE
4. EMOTIONAL SUPPORT
5. FINANCIAL SUPPORT

The process identified 31 unmet needs of GvHD patients that fell under 5 key actionable themes required to address those needs.

Almost all related to lack of information and lack of empowerment.

50 years of EBMT – a journey of innovation and hope

The 50th Annual EBMT Meeting, and the very first to be held in Scotland, was opened by the EBMT President, Anna Sureda (Spain) and delegates were welcomed to the city by the Lord Provost of Glasgow.

A representative of the Patient Advocacy Committee (Natacha Bolaños, Spain) and President of the Nurses Group (Michelle Kenyon, UK) also added their welcome, acknowledging the significant progress EBMT had made over the past 50 years in improving patients outcomes.

Dr Sureda emphasised that the 50th anniversary offered an opportunity to celebrate the EBMT community, its role in saving and improving lives, and its continuing journey of innovation and hope into the future.

EBMT Awards

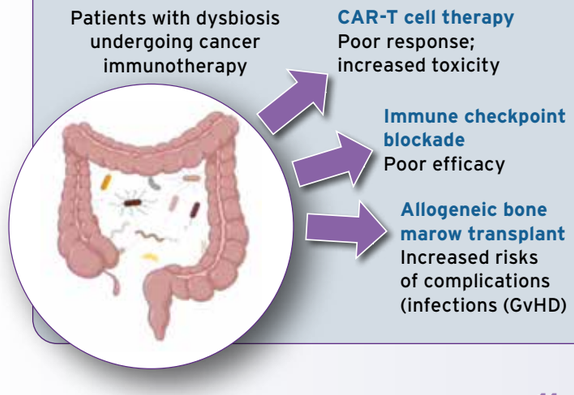
Clinical Achievement Awards, Distinguished Merit Awards and Honorary Membership awards to acknowledge outstanding clinical and scientific contributions to the field of blood and marrow transplantation and cellular therapies were given to six recipients (Table 3).

Table 3. *EBMT Award recipients 2024.*

Clinical Achievement Awards	
Anne Parker (UK)	Implementation of stem cell transplant services in Scotland
Achilles Anagnostopoulos (Greece)	Implementation of stem cell transplant services in Greece and surrounding countries
Distinguished Merit Awards	
Helen Baldomero (Switzerland) Jakob Passweg (Switzerland)	Contribution to the EBMT Activity Survey
Honorary Membership Awards	
Aaron Nagler (Israel); Jane Apperley (UK)	

Figure 5. *Gut microbiome dysbiosis is associated with impaired cancer immunotherapy*

Keynote lecture: The role of the intestinal microbiome in cancer immunotherapy



Marcel van den Brink (USA) provided a comprehensive overview of the latest research into the impact of gut microbiome dysbiosis on the efficacy and outcomes of cancer immunotherapy (Figure 6).

Novel therapeutic approaches to target the dysfunctional microbiota are now under investigation, including rationally-designed probiotics containing specific microbial strains.

IMPORTANT SAFETY INFORMATION FOR THE THERAKOS™ PHOTOPHERESIS PROCEDURE

Indications

The THERAKOS™ CELLEX™ Photopheresis System is indicated for patients older than 18 years of age for the administration of photopheresis in the following:

- Cutaneous T Cell Lymphoma (CTCL)
- Solid Organ Transplant Rejection (SOT) (heart, lung)

The THERAKOS™ CELLEX™ Photopheresis System is indicated in patients older than 3 years of age for the management of:

- Acute and Chronic Graft versus Host Disease (aGvHD, cGvHD)

Contraindications

THERAKOS™ Photopheresis is contraindicated in:

- Patients possessing a specific history of a light sensitive disease
- Patients who cannot tolerate extracorporeal volume loss or who have white blood cell counts greater than 25,000 / mm^3
- Patients who have coagulation disorders or who have previously had a splenectomy

Warnings and Precautions

THERAKOS™ Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure.

- Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image, or may not function properly.
- Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft versus Host Disease (GvHD). Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- When prescribing and administering THERAKOS™ Photopheresis for patients receiving concomitant therapy, exercise caution when changing treatment schedules to avoid increased disease activity that may be caused by abrupt withdrawal of previous therapy.

Adverse Events

- Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for hypotension.
- Transient pyretic reactions, 37.7–38.9°C (100–102°F), have been observed in some patients within six to eight hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction.
- Treatment frequency exceeding labelling recommendations may result in anaemia.
- Venous access carries a small risk of infection and pain.

Please refer to the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual for a complete list of warnings and precautions.

IMPORTANT SAFETY INFORMATION FOR METHOXSALEN USED IN CONJUNCTION WITH THERAKOS™ PHOTOPHERESIS

Consult the 8-methoxypsoralen (Methoxsalen (20 micrograms / mL)) professional leaflet or the oral 8-methoxypsoralen formulation package insert before prescribing or dispensing any medication.

Warnings and Precautions

- Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinoma should be diligently observed and treated.
- Methoxsalen may cause fetal harm when given to a pregnant woman. Women undergoing photopheresis should be advised to avoid becoming pregnant.
- Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic.
- Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

Refer to the package insert for methoxsalen sterile solution (20 micrograms / mL) or the oral 8-methoxypsoralen dosage formulation for a list of all warnings and precautions.

References

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Therakos would like to thank all speakers and attendees who participated during the meeting, contributing to an atmosphere of lively scientific debate and collaboration.

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