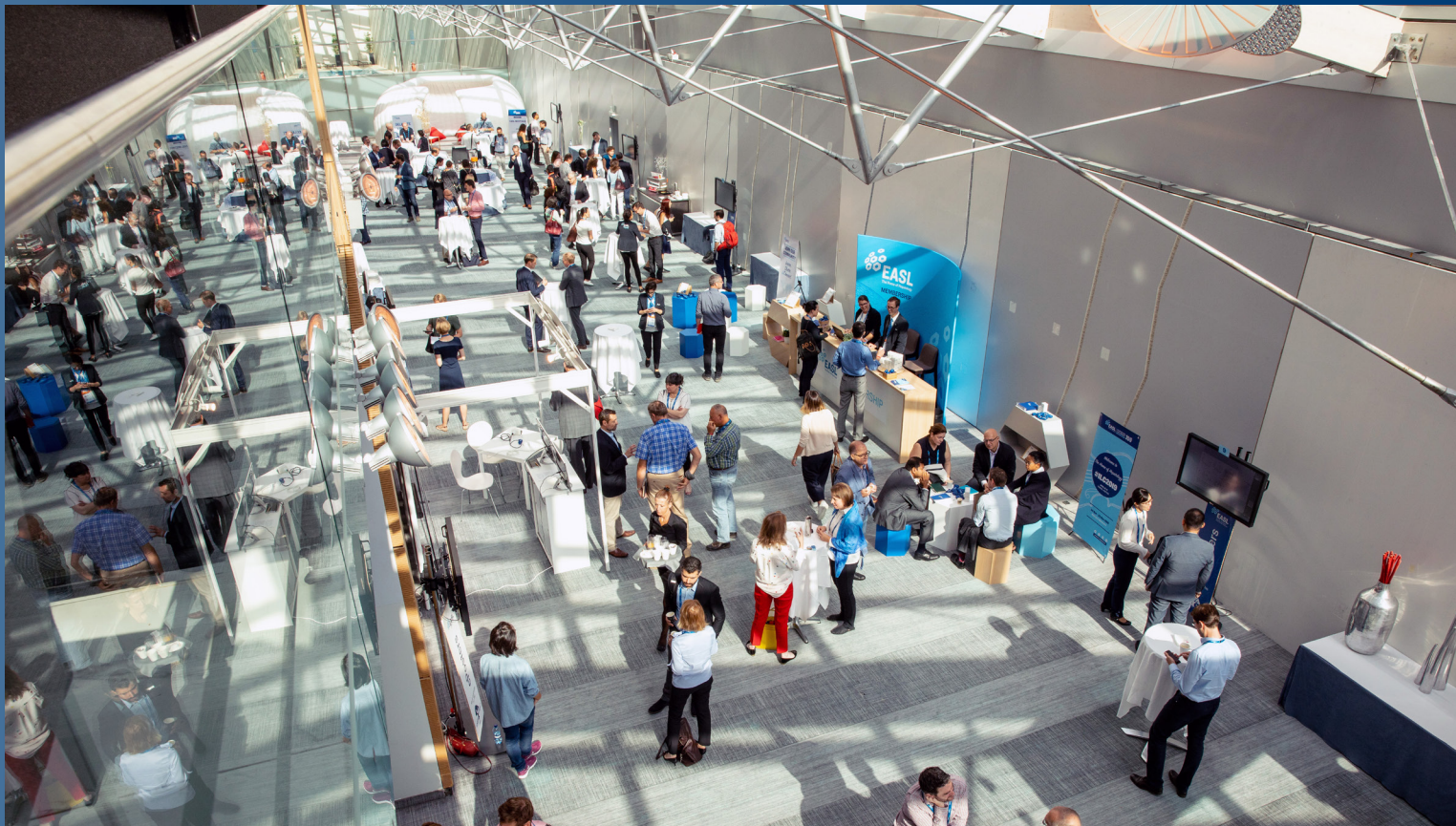


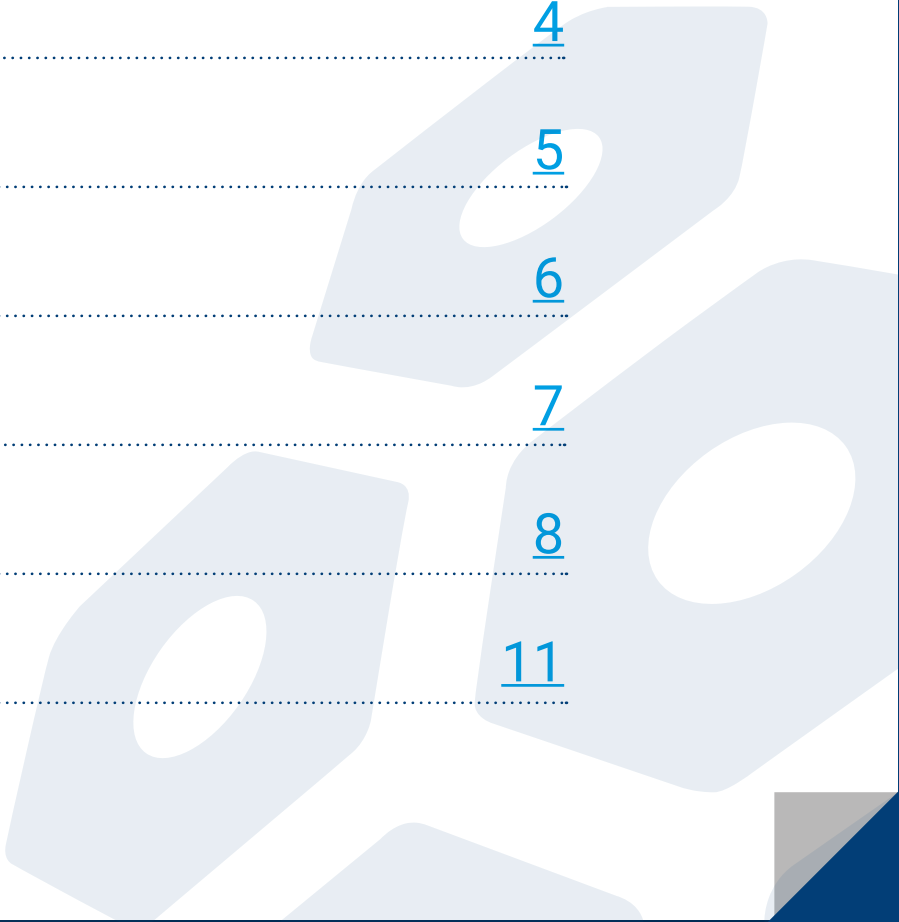
EASL NAFLD SUMMIT 2018

INDUSTRY HIGHLIGHTS



CONTENTS

Thank You	<u>3</u>
Meeting Highlights	<u>4</u>
In Focus With: VLVbio	<u>5</u>
In Focus With: GILEAD	<u>6</u>
In Focus With: ENDRA	<u>7</u>
Scientific Programme Highlights	<u>8</u>
Sponsorship & Exhibition Opportunities	<u>11</u>



THANK YOU



On behalf of the European Association for the Study of the Liver (EASL), we would like to extend a huge thank you to all of our partners that supported the Non-Alcoholic Fatty Liver Disease (NAFLD) Summit in Geneva from September 20-22, 2018.

NAFLD has become a leading cause of chronic liver disease globally, given the alarming rise in levels of obesity and type 2 diabetes mellitus. It presents unique challenges to the hepatology community due to the complex, multi-factorial origins of obesity and the metabolic syndrome, as well as the presence of multiple co-morbidities in many NAFLD patients. There remains many challenges, such as the identification of at-risk individuals, the development of lifestyle and pharmacological therapies and, ultimately, the assessment of cost-effectiveness.

The Summit covered the whole spectrum of basic and clinical aspects of NAFLD, including views from patient groups and the latest advancements in new therapeutic developments. The unique meeting featured multiple case conferences that explored the key issues in the management of patients, with keynote speakers providing the evidence to support decision making and discussions that resulted in a series of consensus statements to facilitate the provision of best practice. Central to the Summit was the concept of multi-disciplinary care, which is of major importance in NAFLD.

The significant representation from industry partners stimulated joint efforts in addressing the key challenges across the spectrum of NAFLD and, throughout the meeting, active audience participation allowed the fostering of greater research collaborations between academia and industry.

The combination of high quality and interactive presentations by leading scientists and clinicians from both academia and industry brought together a variety of stakeholders with an interest in NAFLD care, service and research. The Summit furthered our knowledge and understanding of NAFLD and has helped to identify and prioritise the key future areas for drug development.

Such a successful meeting would not be possible without the essential support of our partners and we hope that all sponsors and exhibitors found the NAFLD Summit as valuable as we did.

We look forward to working with you again soon.

The Scientific Committee,

Elisabetta Bugianesi

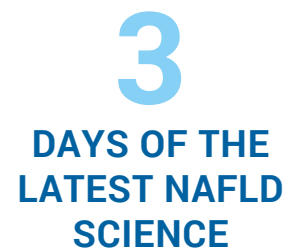
Philip Newsome

Vlad Ratziu



MEETING HIGHLIGHTS

EASL NAFLD SUMMIT 2018 IN NUMBERS



IN FOCUS WITH: VLVbio

VLVbio have been attending EASL events for more than five years and now exhibit at both Monothematic EASL Conferences and the International Liver Congress.

At the EASL NAFLD Summit, Giannella Coghlan (Director of Commercial Operations) explained, "Exhibiting at the EASL NAFLD Summit provides us with the opportunity to engage with key opinion leaders in our speciality. People see us and are aware that we're here so attending these meetings is therefore very worthwhile as we can further our relationships with key speakers."

"The presenters here are excellent. Even if you are not fully updated on their particular topic, they present their content in a way that can be digested by all attendees, so it's easy to follow. Content on Friday afternoon regarding 'Current clinical management of pre-cirrhotic NAFLD' and 'Using pathogenesis to develop new therapies' was a highlight for us as it relates to our key target audience."

"Our expectations are continually high for EASL events, but the EASL team always meet them. No matter the size of an organisation, the EASL staff make solutions and spend time ensuring that we are fully satisfied with our experience, which makes us want to work with them even more."

VLVbio

About VLVbio:

VLVbio offer unique assays for accurate and non-invasive detection of liver damage and disease. Their biomarker assays, M30 and M65, are used globally by academia, industry and healthcare providers, in liver disease areas such as NAFLD, DILI and ASH.



IN FOCUS WITH: GILEAD

Gilead, who have a well-established heritage in liver disease, have been attending and supporting EASL events now for a number of years. "The EASL NAFLD Summit achieved a wonderful balance between providing practical information for physicians, and interesting NAFLD developments from an industry perspective" explained Saj Hansraj (Liver Disease, NASH, Commercial Operations – EMEA Region). "We're witnessing a great increase in knowledge and awareness of the disease, but part of what that increased knowledge shows is that this is an area where there are considerable unmet medical needs. There is a lot to be done to improve the lives of patients."

"I really enjoyed the scientific content of the Summit. The selection of topics and the way the agenda flowed was insightful. For me, some of the most interesting sessions were those relating to the Liver Foundation Study and obesity and public health in relation to NAFLD."

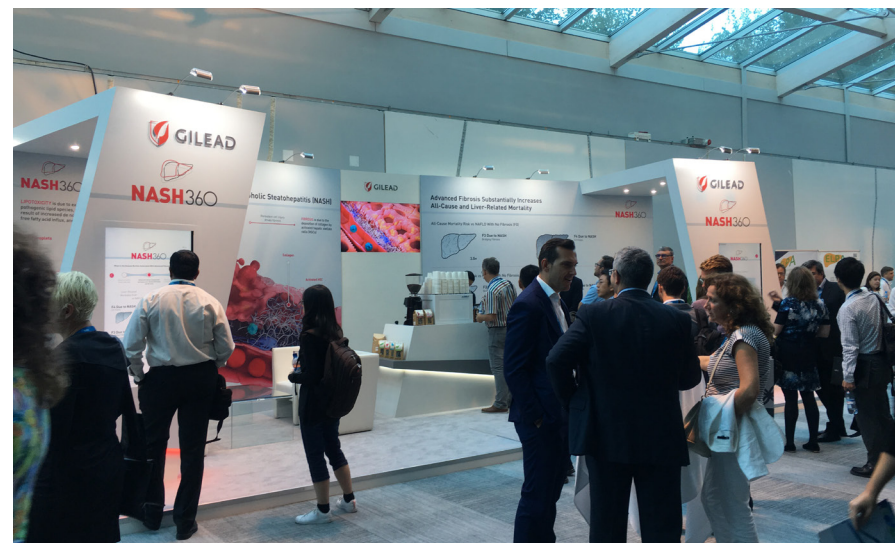
"This is my first time at an EASL Summit and it has been a very positive experience. Developments in relation to NAFLD are moving very quickly and I'm looking forward to seeing how this field evolves in the coming years."

"I'd like to congratulate the organisers on arranging such an interesting and well executed meeting."



About Gilead:

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com



IN FOCUS WITH: ENDRA

ENDRA are currently developing a next generation Thermo-Acoustic Enhanced Ultrasound (TAEUS™) platform, designed to put more information in the hands of doctors and broaden patient access to enhanced healthcare. ENDRA exhibited at an EASL event for the first time at the NAFLD Summit in Geneva, with the objective of building pre-commercial awareness for the TAEUS™ application within the hepatology community.

Richard Moss, Commercial Advisor at ENDRA, commented “Exhibiting at the Summit provided us with the opportunity to discuss our new platform with key opinion leaders and clinicians in the NAFLD field. This enabled us to secure clinical and pre-commercial feedback for ENDRA’s technology and advance our knowledge on the latest NAFLD clinical research. The content presented at the meeting provided a nice combination of knowledge-sharing and interactivity, allowing us to obtain up-to-date information that will support the TAEUS™ launch next year.”

Michael Thornton, Chief Technology Officer at ENDRA, added, “Research is advancing quickly in understanding the onset and progression of NAFLD. Focused meetings like the EASL NAFLD Summit provide ENDRA Life Sciences with the most up to date research and access to the leading health care practitioners and scientists in the field”.



About ENDRA:

ENDRA Life Sciences Inc. (NASDAQ: NDRA) is a developer of enhanced ultrasound technologies. The ENDRA TAEUS™ platform will enable clinicians to visualize human tissue composition, function and temperature in ways previously possible only with CT & MRI - at a fraction of the cost, and at the point-of-care. ENDRA's first TAEUS application, launching in 2019, will focus on the quantification of fat in the liver, for early detection and monitoring of Non-Alcoholic Fatty Liver Disease (NAFLD). ENDRA's goal is to bring new capabilities to ultrasound - thereby broadening access to better healthcare



SCIENTIFIC PROGRAMME HIGHLIGHTS

THURSDAY, 20 SEPTEMBER

Words of Welcome

On behalf of the EASL Governing Board, Frank Tacke welcomed all delegates to the 2nd NAFLD Summit. Opening the meeting, he commented, "EASL is very interested in driving the developments in the field of NAFLD and this meeting allows our community to discuss the clinical developments and scientific advancements in this field. We're very happy to host the annual NAFLD Summit that we established last September and warmly welcome you to Geneva, the hometown of EASL. I would like to give special thanks to the three organisers – Elisabetta Bugianesi, Phillip Newsome and Vlad Ratziu – for putting together this excellent programme.

Phillip Newsome (EASL Vice-Secretary) explained, "This meeting really reflects our long-term commitment to education, training and research in the sphere of NAFLD so we're delighted to see that we have over 370 delegates in attendance this year, along with more 80 abstract submissions. My co-organisers and I have looked to create a programme that gives attendees the full spread, including discovery science, interaction with industry, clinical case scenarios and also policy perspectives on NAFLD."

"We also wanted to really focus on two elements; to what extent are the NAFLD clinical practice guidelines followed and to explore the significant developments in NAFLD over the past year. It's a really exciting time in this field and we really want to pick out these key elements."

The Clinical Picture of NAFLD/NASH

Opening this session, Quentin Anstee (Newcastle University, UK) discussed how the natural history of NAFLD/NASH progression is much more dynamic than has previously been appreciated and that there are a huge number of modifiers, both genetic and environmental, that need to be considered to help us stratify our patients.

From a public health perspective, Harry Rutter (University of Bath, UK) provided an insightful presentation on the incredibly strong link between obesity and liver disease. Alarming increases in the global levels of childhood obesity were presented and Harry Rutter commented on how the world around us has changed. "Obesity is a normal response, by normal people, to an abnormal environment" he explained and that "areas that we need to focus on now in tackling obesity are like building the foundations of a building". Current research is biased towards achieving short-



term results from individual level interventions, rather than focusing on a long-term obesity strategy that should be implemented over decades.

Jacob George (University of Sydney, Australia) explored the healthcare and economic burden of NAFLD and NASH, including the current prevalence of NAFLD and projected trends for the future. He reported on how

chronic liver disease affects more people worldwide (844 million) than pulmonary disease (650 million), cardiovascular disease (540 million) and diabetes (422 million) and how physical inactivity is, along with obesity, a huge driver for NAFLD.

A further highlight during this session was provided by Frank Tacke, who revealed the preliminary results of the NAFLD Policy Review for the first time in public. A survey, conducted by EASL, was undertaken to evaluate the extent to which EU member states have key policies and guidelines in place to address NAFLD/NASH and to identify the gaps and opportunities to improve these guidelines. Out of the eight participating countries, none had a written national NAFLD/NASH action plan, although NAFLD/NASH is accounted for in some action plans concerning obesity, alcohol and cardiovascular disease.

Frank Tacke explained that the next steps in this process are to expand the survey into the remaining EU-28 countries and beyond and to utilise the data for targeted interventions and advocacy purposes. "There are high levels of uncertainty in the management of NAFLD patients, especially regarding structured treatments, when to refer patients and when to screen for disease complications" he stated. "There is a low awareness in NAFLD/NASH across Europe and we need to encourage key stakeholders to start tackling this disease on a broader level."

SCIENTIFIC PROGRAMME HIGHLIGHTS

Case-finding for NAFLD/NASH

This session covered how different cases are presented by patients, from typical cases to ones that require specialist input from hepatologists. Emmanuel Tsochatzis (University College London, UK) explained how there are recommendations to test for advance fibrosis in people with NAFLD and discussed whether we should be screening for advanced fibrosis in people at risk. Emmanuel Tsochatzis concluded that the choice of non-invasive tests in screening for advance fibrosis should be based on local availability and expertise and called for more data on the effectiveness and cost-effectiveness in doing so.

Roy Taylor (Newcastle University, UK) provided insight into diabetes and NAFLD, explaining that type 2 diabetes has always been a “misunderstood disease. He discussed the strong relationship between diet, body weight and liver fat, explaining that one third of people with type 2 diabetes can normalise their liver fat to optimal levels by losing weight.

Non-invasive methods and biomarkers in NASH were also explored in this session. Jerome Boursier (Angers University, France) explained the “challenging” management in non-invasive methods, calling on the importance of screening in high-risk populations to educate healthcare professionals and to demonstrate the ability to monitor disease progression to help to adapt treatments.

FRIDAY, 21 SEPTEMBER

NAFLD Mechanisms

The second day of the Summit started with a discovery science session, with key note lectures on the mechanisms of liver injury, fibrosis development and carcinogenesis of NASH. Amalia Gastaldelli (National Research Council, Institute of Clinical Physiology, Italy) opened the session by discussing the metabolic pathway concerning insulin resistance and lipotoxicity. She explained that, in subjects with NAFLD, insulin resistance is pronounced at the level of the muscle, where glucose uptake is reduced, but it is present also in the liver, where insulin does not properly suppress hepatic glucose production and in the adipose tissue, where peripheral lipolysis is high despite high insulin concentrations.

Another highlight in Friday's programme was a talk on the relationship between the gut and the liver by Herbert Tilg (Innsbruck Medical University, Austria). “Gut-liver interactions, in my view, substantially impact NAFLD, although research is still in a rather descriptive stage”, explained Tilg. This was followed with insightful presentations from Detlef Schuppan (University Medical Centre Mainz, Germany) and Jessica Zucman-Rossi (University Paris Descartes), who discussed the mechanisms of fibrogenesis in NASH and the carcinogenesis of NASH respectively.

An industry perspective was also provided on the best animal model for NASH research. Here, Keld Fosgerau (Gubra, Denmark) explained that several animal models for NASH are available with varying aspects of the human disease and that approaches involve diet or chemically induced, nutrient deficient and genetic or in-bred models. He added that the model should be readily accessible, well defined and described, as well as present with reproducible endpoints.

The Patient Perspective

A clinically focussed session then followed that examined patient-reported outcome measures in NAFLD, giving perspectives from the European Liver Patient Association (ELPA) and the European Medicines Agency (EMA). Within this session, Zobair Younossi (Virginia Commonwealth University, USA) explored patient-reported outcomes within a wider spectrum of outcomes, including clinician-reported outcomes, caregiver-reported outcomes and physiological outcomes. “There are quite a lot of discrepancies between what physicians actually feel is important for patients and what patients feel”, he explained. “Patient-related outcomes act as a predictor for disease prognosis and mortality, are important from a policy perspective and also help to capture the comprehensive burden of NASH and the impact of its treatment on patients’ experience.”

“It's important to remember that at some point in our lives, we are all patients”, explained Marko Korenjak (Vice President, ELPA). He discussed basic patient problems regarding NAFLD, which involve the different healthcare professionals available to consult with, including hepatologists, nutritionists and gastroenterologists, and how this can be confusing for patients. Marko Korenjak advised that we need to continue collaboration on patient involvement in research and provide patients across Europe with clear and easy to understand information regarding NAFLD and NASH.

SCIENTIFIC PROGRAMME HIGHLIGHTS

SATURDAY, 22 SEPTEMBER



The Treatment of NAFLD

The final day of the meeting began with a state-of-the-art talk on promising drug development in NAFLD, with talks on licensing end-points, the scope for sequential or combination therapy and a presentation on assessing cost-effectiveness in NAFLD. Discussing drug development for treating NASH, Vlad Ratziu (Sorbonne University, France) commented "The times ahead are fascinating because of the intersection between clinical research and complicated biology and due to the prospects for therapy in patients with NASH. A lot of work still needs to be done on biomarkers, both to diagnose the disease and to characterise the patient heterogeneity."

During this session, Aditi Saxena (Internal Medicine Research Unit, Pfizer, USA) provided insight into the challenges presented by sequential or combination therapy. "We understand that this

is a complex disease pathogenesis and that there are multiple pathways and possible targets available for combination therapy" stated Aditi Saxena. "Ultimately, organisations have to demonstrate the plausible biologic rationale for the targets that they are choosing. Regulatory guidance does provide alignment in the approaches to fixed-dose combinations of new chemical entities and the end point in clinical trials must be considered. In terms of clinical practice, the clinical trials should be providing guidance to the ultimate providers who will be using these therapies to treat patients with NASH." The session then culminated in a consensus statement on the treatment objectives of pharmacological interventions in NAFLD.

The final presentations of the meeting explored the clinical challenges of patients with decompensated NASH cirrhosis and their consideration for liver transplantation. A clinical case was presented by Patrizia Burra (Padua University Hospital, Italy) on a patient with decompensated NASH, followed by a discussion from Manuel Romero Gomez (University of Seville, Spain) on assessing risk in NASH patients for transplant and an informative talk from Paolo Muesan (University of Birmingham, UK), on the outcomes and complications in transplantations for NAFLD.

Following a discussion on evolving evidence that examined which NASH patients should be considered for transplantation, the meeting was closed by Elisabetta Bugianesi, who thanked all participants and organisers for contributing to such an excellent Summit.



SPONSORSHIP & EXHIBITION OPPORTUNITIES

NALFD SUMMIT 2019 - JOIN US IN SEVILLE!

The next NAFLD Summit will take place in Seville on the 26-28 September, 2019. For more information on sponsorship and exhibition opportunities at the NAFLD Summit 2019, please contact the EASL Fundraising and Corporate Relations Team.

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NAFLD summit 2019

26-28 SEPTEMBER
SEVILLA, SPAIN

Scientific Organising Committee

Prof. Isabelle Leclercq, *Belgium*

Prof. Massimo Pinzani, *United Kingdom*

Prof. Manuel Romero-Gomez, *Spain*

Dr Joern Schattenberg, *Germany*

SAVE THE DATE