

## SATELLITE SYMPOSIUM PROGRAM AND AGENDA (as of May 20, 2019)

### Tuesday, June 18, 2019

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13:30 – 15:00

2 *parallel symposia*

#### Room B I

##### **KITE, A GILEAD COMPANY**

##### **CAR T: FROM BED TO BENCH AND BACK AGAIN**

Chair: C. Roddie, London (UK)

The journey of CAR T therapy from apheresis to processing and back for infusion is complex with many considerations including logistics and GMP-compliance requirements. Furthermore, there are challenges associated with scalability including the ability to increase manufacturing capacity without compromising quality. This symposium will discuss many of the key considerations associated with manufacturing CAR T therapies and explore potential methods to overcome them including automation. This will help ensure successful and timely delivery of CAR T to as many patients as possible. Use of non-conforming or out of specification products in the clinic will also be discussed.

##### INTRODUCTION

C. Roddie, London (UK)

##### OVERVIEW OF DEVELOPMENT JOURNEY: FROM BENCH TO BEDSIDE

J. Rossi (United States)

##### FROM PATIENT TO COMMERCIAL PRODUCTION: APHERESIS TO SAMPLE SHIPPING

C. Roddie, London (UK)

##### FROM SAMPLE RECEIPT TO CAR T PRODUCT

C. Shen and L. van de Wiel (The Netherlands)

##### PRODUCT RELEASE TESTS: HELPING ENSURE PATIENT SAFETY AND GUARANTEEING QUALITY

C. Chabannon, Marseilles (France)

##### SCALING CAR T FOR A GMP STANDARD PRODUCT

C. Roddie, London (UK)

#### Room B II

##### **PFIZER ONCOLOGY**

##### **RITUXIMAB BIOSIMILAR: AN OPPORTUNITY TO FOSTER INNOVATION IN LYMPHOMA TREATMENT**

Chair: J. Sharman, Eugene, OR (USA)

Rituximab based therapies is in many instances the standard-of-care approach for patients with FL, DLBCL and CLL. In some patients Chemo-free Rituximab combination therapy may be the most appropriate. However, the increase cost of biologics could potentially be a limiting factor to improve patient's outcomes world-wide. The utilization of Rituximab Biosimilar may offer the opportunity to upgrade patient access to expensive treatments. In addition, given the landscape of the Biosimilars field, rigorous and well-designed RWE Biosimilar studies are critical to address data gaps and obtain

coverage upon evidence generation. The adoption of Rituximab Biosimilar may help to meet high medical needs while maintaining affordability.

- 13:30 WELCOME AND INTRODUCTION  
J. Sharman, Eugene, OR (USA)
- 13:40 BIOSIMILAR: "DO BIOSIMILARS HAVE SIMILAR SAFETY PROFILE AND EFFICACY"? CURRENT PERSPECTIVE  
J. Goncalves, Lisboa (Portugal)
- 14:00 REAL WORD EVIDENCE IN BIOSIMILARS. DECISION MAKING IN THE REAL-WORLD  
A. Mato, New York, NY (USA)
- 14:20 RITUXIMAB BIOSIMILAR IN FOLLICULAR LYMPHOMA. EARLY USE OF RITUXIMAB  
J. Sharman, Eugene, OR (USA)
- 14:40 PANEL DISCUSSION  
All
- 16:00 – 17:30 *3 parallel symposia*
- Room A** **NOVARTIS ONCOLOGY**  
**MAXIMIZING CLINICAL BENEFIT IN LYMPHOMAS: EXPLORING THE UTILITY OF CAR T-CELL THERAPY**  
Chair: U. Jäger, Vienna (Austria)
- In the satellite symposium "Maximizing Clinical Benefit in Lymphomas: Exploring the Utility of CAR-T Cell Therapy," Dr. Ulrich Jäger (chair) and additional faculty will lead an interactive discussion regarding the role of CAR-T cell therapy in lymphomas. Key themes addressed will include defining the diffuse large B-cell lymphoma continuum of care and best practices for adverse event management; in addition, the potential future utility of CAR-T cell therapy in non-Hodgkin lymphoma – including combination partners, use in earlier lines of therapy, and role for pediatric patients – will be covered.
- 16:00 – 16:05 INTRODUCTIONS AND OPENING REMARKS  
U. Jäger, Vienna (Austria)
- 16:05 – 16:25 DEFINING THE UTILITY OF CAR-T CELL THERAPY IN THE DLBCL CONTINUUM OF CARE  
U. Jäger, Vienna (Austria)
- 16:25 – 16:45 EXPLORING ADDITIONAL ROLES FOR CAR-T CELL THERAPY IN NHL  
A. Sureda, Barcelona (Spain)
- 16:45 – 17:00 RATIONALE AND FUTURE DIRECTIONS FOR CAR-T CELL THERAPY IN PEDIATRIC NHL  
K. Curran, New York, NY (USA)
- 17:00 – 17:15 PRACTICAL CONSIDERATIONS FOR TOXICITY MANAGEMENT WITH CAR-T CELL THERAPY  
S. Schuster, Philadelphia, PA (USA)
- 17:15 – 17:25 PANEL DISCUSSION AND Q&A  
All
- 17:25 – 17:30 CLOSING REMARKS  
U. Jäger, Vienna (Austria)

**Room B I****BRISTOL-MYERS SQUIBB****RATIONALE: RESEARCH AND NEW THERAPEUTIC APPROACHES – I-O NOVEL AGENTS ADVANCING LYMPHOMA EXPECTATIONS**

Chair: P.L. Zinzani, Bologna (Italy)

This symposium, sponsored by Bristol-Myers Squibb, describes recent advances in treating patients with lymphoma using immuno-oncology (I-O) agents and the utilization of biomarkers to further understand the underlying disease biology and inform novel targeting strategies. Following an introduction to I-O clinical trial advances and ongoing investigations, there will be a discussion of recent key data in salvage and maintenance settings and their potential impact on post-transplant treatment. The final presentation will focus on the potential of biomarkers in lymphoma to inform future clinical trials. A question-and-answer session will provide an opportunity for the participants to interact with the faculty experts.

- 16:00 – 16:05 WELCOME AND INTRODUCTIONS  
P.L. Zinzani, Bologna (Italy)
- 16:05 – 16:25 ONGOING IMMUNO-ONCOLOGY EXPLORATIONS IN LYMPHOMA  
P.L. Zinzani, Bologna (Italy)
- 16:25 – 16:45 OPTIMIZING PERI-TRANSPLANT THERAPY WITH IMMUNO-ONCOLOGY  
A. Herrera, Duarte, CA (USA)
- 16:45 – 17:05 BIOMARKER DISCOVERY IN LYMPHOMA  
B. Chapuy, Göttingen (Germany)
- 17:05 – 17:25 OPEN DISCUSSION WITH THE EXPERTS  
All
- 17:25 – 17:30 CLOSING REMARKS  
P.L. Zinzani, Bologna (Italy)

**Room B II****KITE, A GILEAD COMPANY****CAR T THERAPY: A CLOSER LOOK AT THE SCIENCE BEHIND THE CELLS**

Chair: M. Topp, Würzburg (Germany)

The science surrounding CAR T response and safety profiles is still emerging. During this highly interactive symposium, factors involved in these outcomes including biomarkers of response to treatment as well as the potential underlying mechanisms for common toxicities will be discussed. This symposium will also look at future developments and see how outcomes for patients may be improved with CAR T technologies including third generation-, dual antigen specific-CARs and TRUCKs. We encourage you to take the opportunity to ask our experts questions and learn more about the scientific advancements for these novel therapies for patients treated with CAR T.

**INTRODUCTION AND OVERVIEW**

M. Topp, Würzburg (Germany)

**INTEGRATING KEY TRANSLATIONAL FINDINGS WITH PATIENT OUTCOMES**

C. Bonini, Milan (Italy)

**UNDERSTANDING FACTORS LEADING TO NON-RESPONSES**

M. Topp, Würzburg (Germany)

Q&A AND PANEL DISCUSSION  
All

THE FUTURE OF CAR T THERAPY  
Karl Peggs, London (UK)

Q&A AND PANEL DISCUSSION  
All

18:30 – 20:00

*4 parallel symposia*

**Room A**

**ROCHE**

**ANTIBODY THERAPIES FOR PATIENTS WITH DLBCL: WHAT DOES THE FUTURE HOLD?**

Chair: L. Sehn, Vancouver B.C. (Canada)

While many patients with diffuse large B-cell lymphoma (DLBCL) can be cured with current front-line therapy, a significant proportion relapse or are refractory to treatment. High-dose chemotherapy and stem-cell transplantation are possible for some of these patients, but many are ineligible due to co-morbidities or disease refractory to chemotherapy; these patients face a dismal outcome. An international faculty of experts will discuss treatment and management of both front-line and relapsed/refractory DLBCL, with a focus on novel antibody therapies. Join us to examine how the DLBCL landscape may evolve in the near future as new data and treatment options become available.

18 :30 – 18 :35

INTRODUCTION

L. Sehn, Vancouver B.C. (Canada)

18 :35 – 18 :45

WHAT OPTIONS DO OUR PATIENTS HAVE FOR FIRST-LINE TREATMENT?

A. Lopez Guillermo, Barcelona (Spain)

18:45 – 18:55

WHAT'S NEXT FOR PATIENTS WHO RELAPSE OR ARE REFRACTORY TO TREATMENT?

M.J. Matasar, New York, NY (USA)

18:55 – 19:10

CAN NOVEL ANTIBODY THERAPIES IMPROVE OUTCOMES FOR PATIENTS WITH R/R DLBCL?

F. Morschhauser, Lille (France)

19:10 – 19:25

POLATUZUMAB VEDOTIN: CLINICAL DATA IN R/R DLBCL

L. Sehn, Vancouver B.C. (Canada)

19 :25 -19 :40

WHAT MIGHT THE FUTURE HOLD FOR DLBCL TREATMENT STRATEGIES?

A. McMillan, Nottingham (UK)

19:40 – 19:55

PANEL DISCUSSION

All

19:55 – 20:00

CLOSING REMARKS

L. Sehn, Vancouver B.C. (Canada)

**Room B I**

**BAYER**

**PRECISION MEDICINE IN MALIGNANT LYMPHOMA: IS IT A REALITY?**

Chair: M. Ghilmini, Bellinzona (Switzerland)

Precision medicine has traditionally been a personalized approach to the treatment of solid tumors with the advent of biomarker-driven strategies. However, when it comes to

the treatment of malignant lymphoma, is precision medicine a reality? Join the esteemed faculty Dr. Michele Ghilmini, Dr. Margaret Shipp, Dr. Louis Staudt, and Professor Martin Dreyling in their invigorating exploration of genetic heterogeneity in aggressive lymphoma, clinical exploration of precision medicine in DLBCL, and enrichment strategies in indolent lymphoma with the aim of uncovering whether precision medicine is a reality in malignant lymphoma.

WELCOME AND OPENING REMARKS

M. Ghilmini, Bellinzona (Switzerland)

GENETIC HETEROGENEITY IN AGGRESSIVE LYMPHOMA AND POTENTIAL THERAPEUTIC IMPLICATIONS

M. Shipp, Boston, MA (USA)

CLINICAL EXPLORATION OF PRECISION MEDICINE IN DLBCL

L. Staudt, Bethesda, MD (USA)

PATIENT ENRICHMENT STRATEGIES AND THERAPY SELECTION IN MALIGNANT LYMPHOMAS

M. Dreyling, Munich (Germany)

PANEL DISCUSSION/Q&A

Chair: M. Ghilmini, Bellinzona (Switzerland)

**Room B II**

**TAKEDA ONCOLOGY**

**ON THE FRONTLINE: MANAGING PATIENTS WITH CD30+ HL AND PTCL**

Chair: M. Hutchings, Copenhagen (Denmark)

This satellite symposium supported by Takeda Oncology aims to highlight the current treatment landscape and recent developments in frontline CD30+ HL and PTCL. The latest data from studies in frontline CD30+ HL and PTCL will be discussed, as well as challenges and management strategies for patients in these settings. This symposium will be highly interactive with opportunities for the audience to tailor the topic of discussion during each presentation. There will also be a dedicated question and answer session to enable open interaction between the participants and the faculty.

18:30 – 18:35

WELCOME AND INTRODUCTION

M. Hutchings, Copenhagen (Denmark)

18:35 – 18:55

TAILOR-THE-TOPIC: HL DISCUSSIONS

M. Hutchings, Copenhagen (Denmark)

18:55 – 19:15

THE LATEST RESULTS IN THE MANAGEMENT OF FRONTLINE CD30+ HL

J.M. Connors, Vancouver BC (Canada)

19:15 – 19:35

CURRENT LANDSCAPE AND RECENT DEVELOPMENTS IN THE FRONTLINE MANAGEMENT OF CD30+ PTCL

S. Horwitz, New York, NY (USA)

19:35 – 19:55

PANEL Q&A

Faculty, facilitated by M. Hutchings, Copenhagen (Denmark)

19:55 – 20:00

SUMMARY AND CLOSE

M. Hutchings, Copenhagen (Denmark)

**LYMPHOMA HUB**

**NEW CHEMOTHERAPY-FREE APPROACHES FOR THE TREATMENT OF  
LYMPHOID MALIGNANCIES**

Chair and co-chair: G. Salles, Lyon (France) and A. Younes, New York, NY (USA)

This symposium brings together [an international panel of experts](#) who will discuss the novel chemotherapy-free treatment approaches for lymphoid malignancies.

Presentations will focus on diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic lymphoma, navigating the rapidly evolving treatment landscapes. The new chemotherapy-free treatment options will be explored alongside the current standards of care. Each presentation will be followed by a question and answer session to allow for discussion with the expert panel. [Come and join the debate](#) on whether it is possible to switch to the chemotherapy-free agents.

For more information visit: <https://icml.lymphomahub.com/>

18:30–18:35	OBJECTIVES AND INTRODUCTIONS G. Salles, Lyon (France)
18:35 -18:45	DLBCL – CHEMOTHERAPY-FREE REGIMENS: PROS AND CONS U. Jäger, Vienna (Austria)
18:45 –18:55	ROUND TABLE ON DLBCL All
18:55 –19:05	FL – CHEMOTHERAPY-FREE REGIMENS: PROS AND CONS N. Fowler, Houston, TX (USA)
19:05 –19:15	ROUND TABLE ON FL All
19:15–19:25	MCL – CHEMOTHERAPY-FREE REGIMENS: PROS AND CONS S. Rule, Plymouth (UK)
19:25 –19:35	ROUND TABLE ON MCL All
19:35 – 19:45	CLL – CHEMOTHERAPY-FREE REGIMENS: PROS AND CONS M. Hallek, Cologne (Germany)
19:45 – 19:55	ROUND TABLE ON CLL All
19:55 – 20:00	MEETING CONCLUSION A. Younes, New York, NY (USA)

18:30 – 20:00 3 parallel symposia

### Room A

#### JANSSEN PHARMACEUTICAL COMPANIES OF JOHNSON & JOHNSON

#### CHALLENGING THE STANDARDS OF CARE IN THE MANAGEMENT IN B-CELL LYMPHOMAS

Co-chairs: C. Buske, Ulm (Germany) and S. Rule, Plymouth (UK)

Therapeutic advances in lymphoma have been made over many decades. A deeper understanding of disease pathogenesis guided the development of targeted therapies for patients with MCL and WM. Consequently, providing tolerable and curative therapies to many lymphoma patients is now possible. However, some specific challenges still remain, including limited investigations into rare lymphoma subtypes and using backbone chemotherapy regimens for initial therapy. Our faculty will discuss studies challenging current standards of care and the potential to improve patient outcomes in various B-cell lymphomas.

18:30-18:40

WELCOME AND INTRODUCTION

C. Buske, Ulm (Germany)

18:40-19:00

HOW ARE TARGETED THERAPIES IMPACTING THE MANAGEMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA (MCL)?

S. Rule, Plymouth (UK)

19:00 – 19:20

CAN WE IMPROVE ON R-CHOP FOR PATIENTS WITH DIFFUSE LARGE B CELL LYMPHOMA (DLBCL)?

G. Lenz, Münster (Germany)

19:20 – 19:40

DOES CHEMOTHERAPY STILL HAVE A ROLE IN WALDENSTRÖM'S MACROGLOBULINEMIA (WM)?

S. Treon, Boston, MA (USA)

19:40 – 20:00

PANEL DISCUSSION AND CLOSING REMARKS

C. Buske, Ulm (Germany) and all

### Room B

#### MEDSCAPE EDUCATION

#### CHALLENGING CURRENT PARADIGMS IN CLL: TIME AND TREATMENT

*Supported by an independent educational grant from AbbVie*

Chair: P. Hillmen, Leeds (UK)

The concept of time-limited therapy is not new; chemotherapy regimens are of fixed duration. However, recent years have seen the emergence of therapies, such as Bruton tyrosine kinase (BTK) inhibitors, which require continuous treatment. In contrast, B-cell lymphoma 2 (Bcl-2)-inhibitor combinations have been developed as 2-year and 1-year fixed-duration therapies, offering new time-limited treatment options. Furthermore, both approaches are – or will potentially be – approved in both front-line and relapse settings, challenging both initial treatment selection and sequencing decisions.

This symposium explores the current and emerging treatment paths for patients with treatment-naïve chronic lymphocytic leukemia (CLL) and the impact of initial choices on treatment options in relapse.

18:30 – 18:40

WELCOME AND INTRODUCTION

P. Hillmen, Leeds (United Kingdom)

18:40-19:00

NOVEL CONCEPTS IN CLL PRACTICE

P. Hillmen, Leeds (United Kingdom)

19:00-19:20

CURRENT AND EMERGING PARADIGMS: TIME-LIMITED THERAPY

B. Eichhorst, Cologne (Germany)

19:20-19:40 CURRENT AND EMERGING PARADIGMS: CHRONIC THERAPY  
M. Davids, Boston, MA (USA)

19:40-20:00 CHALLENGES IN PRACTICE: INITIAL TREATMENT SELECTION AND SEQUENCING THERAPY  
Panel and Audience Debate

**Auditorium,  
USI Università**

**SANDOZ ONCOLOGY**

**VARIABILITY OF BIOLOGICS AND ITS IMPACT ON BIOSIMILAR DEVELOPMENT**

Chair: P. Cornes, Bristol (UK)

Biologics are highly complex to manufacture and their immunogenicity, tolerability, and efficacy profiles can be affected by significant manufacturing process changes. As such, manufacturing changes must be carefully monitored at every step, in order to ensure the correct product identity throughout the lifecycle.

Biosimilars are developed using highly sensitive analytical methods and tailored clinical programs. The advent of biosimilars allowed for a much more detailed analysis of batch-to-batch variability and manufacturing shifts of reference medicines. Recently, some shifts in quality attributes of reference medicines have been reported by biosimilar manufacturers.

The faculty will discuss the potential impact of biologic variability on clinical outcomes and biosimilar development.

(References available on request)

18:30 – 18:45 THE REGULATORY PERSPECTIVE  
H. Schellekens, Utrecht (The Netherlands)

18:45 – 19:00 THE ANALYTICAL PERSPECTIVE  
M. Schiestl, Kundl (Austria)

19:00 – 19:15 THE CLINICIAN'S PERSPECTIVE  
W. Jurczak, Krakow (Poland)

19:15 – 19:30 THE PATIENT PERSPECTIVE  
P. Cornes, Bristol (UK)

19:30 – 20:00 DEBATE AND Q&A  
All faculty



## Thursday, June 20, 2019

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18:30 – 20:00      *2 parallel symposia*

### Room A

#### **CELGENE**

#### **INDIVIDUALIZING TREATMENT AND EMERGING THERAPIES IN B-CELL MALIGNANCIES**

Chair: U. Vitolo, Turin (Italy)

Recent clinical developments are transforming the treatment of indolent and aggressive B-cell malignancies. Chemotherapy-free therapies are altering the therapeutic landscape of both frontline and relapsed/refractory follicular lymphoma. Additionally, frontline treatment of diffuse large B-cell lymphoma is becoming increasingly individualized with a focus on selecting optimal therapies according to cell of origin. Meanwhile, the emergence of CAR T therapies for the treatment of various non-Hodgkin lymphomas and chronic lymphocytic leukemias have the potential to shift treatment paradigms entirely. Key emerging data in B-cell malignancies will be highlighted and discussed by experts in the field.

18:30-18:35      WELCOME AND INTRODUCTIONS  
U. Vitolo, Turin (Italy)

18:35-18:55      TREATMENT IN THE CHEMOTHERAPY-FREE ERA IN FRONT-LINE AND  
RELAPSED AND REFRACTORY FOLLICULAR LYMPHOMA  
J.P. Leonard, New York, NY (USA)

18:55-19:15      OPTIMIZING FRONTLINE DLBCL TREATMENT: THE ROLE OF CELL OF ORIGIN  
U. Vitolo, Turin (Italy)

19:15-19:35      EMERGING ROLE OF CAR T THERAPIES IN THE TREATMENT OF NHL AND CLL  
D. Maloney, Seattle, WA (USA)

19:35 – 20:00      CLOSING AND Q&A  
U. Vitolo, Turin (Italy) and All

### Room B

#### **MORPHOSYS**

#### **SURVIVAL, SAFETY, SIMPLICITY: TRANSFORMING TREATMENT SEQUENCING IN DLBCL**

Co-chairs: B.D. Cheson, Washington DC (USA) and G. Salles, Lyon (France)

Join us for this interactive symposium as we explore DLBCL treatment approaches: the progress made, remaining challenges, and the potential future of the treatment landscape. With an emphasis on the patient journey, we will seek to understand the issues faced beyond the first-line treatment setting, and hear expert insights to navigate real-world treatment decision-making challenges. In addition, through advances in DLBCL disease understanding, we will provide perspectives on how novel treatment approaches may be utilized to achieve new treatment strategies for patients who experience relapsed or refractory DLBCL.

18:30 – 18:35      WELCOME AND INTRODUCTION  
Co-chairs: B.D. Cheson, Washington DC (USA) and G. Salles, Lyon (France)

18:35 – 18:45      DLBCL TREATMENT LANDSCAPE: CURRENT PERSPECTIVE  
G.S. Nowakowski, Rochester, MN (USA)

18:45 – 19:00      THE PATIENT JOURNEY: TREATMENT DECISION MAKING IN REAL-WORLD PRACTICE  
J. Westin, Houston, TX (USA)

19:00 – 19:10	PANEL DISCUSSION All
19:10 – 19:25	THE FUTURE FOR DLBCL: TRANSFORMING OUR APPROACHES AND TREATMENT SEQUENCING? A. Davies, Southampton (UK)
19:25 – 19:40	TARGETING CD19: A NOVEL ANTIBODY STRATEGY G. Salles, Lyon (France)
19:40 – 19:55	PANEL DISCUSSION All
19:55 – 20:00	SUMMARY AND CLOSE B.D. Cheson, Washington DC (USA)

## Friday, June 21, 2019

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Room A  
18:30 – 19:30

### ONCOLOGY INSTITUTE OF SOUTHERN SWITZERLAND – IOSI

#### “THE BIG DEBATE: POINT COUNTER POINT”

#### ARE NEW EXPENSIVE ANTI-LYMPHOMA DRUGS WORTH THE MONEY?

Chair: M. Ghielmini, Bellinzona (Switzerland)

*Supported by Gilead Sciences who provided funding.*

Often targeted therapy, immunotherapy and CAR-T cells are registered at high price for indications for which they have at most demonstrated an increase in PFS and not in OS. The Big Debate, organized by the Oncology Institute of Southern Switzerland (IOSI) has become a tradition, and this year will discuss this issue. In three short debates, 6 distinguished speakers (10 minutes each) will argue, for three different classes of drugs, if the results of new and expensive treatment do or not justify their very high costs.

#### BCR PATHWAY INHIBITORS

Yes: M. Dreyling, Munich (Germany) vs No: A. Davies, Southampton (UK)

#### IMID'S

Yes: S. Rule, Plymouth (UK) vs No: G. Salles, Lyon (France)

#### CART-T CELLS

Yes: A. Sureda, Barcelona (Spain) vs No: L. Sehn, Vancouver B.C. (Canada)