



EPICS

**EPICS CONGRESS
COVERAGE: EHA 2020 –
FOCUS ON NHL/CLL**

June 2020

- > On June 3, 2020, Aptitude Health brought together a group of scientists and clinical investigators with expertise in non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL) to attend an expert panel
- > The goal of the expert panel was to discuss the latest therapeutic developments and translational research in NHL and CLL treatment, apply these advances to dynamic and oftentimes individualized clinical decision-making, and explore how emerging data will affect ongoing research, development of new compounds, and future treatment paradigms

CO-CHAIR

Franck Morschhauser, MD, PhD
Centre Hospitalier Universitaire de Lille
Lille, France

FACULTY

Stephen M. Ansell, MD, PhD
Mayo Clinic
Rochester, MN

Barbara Eichhorst, MD
University of Munich
Munich, Germany

Raul Cordoba, MD, PhD
Fundacion Jimenez Diaz University Hospital
Madrid, Spain

CO-CHAIR

Thomas Witzig, MD
Mayo Clinic
Rochester, MN

Mathias Rummel, MD, PhD
Justus-Liebig University-Hospital
Giessen, Germany

Pier Luigi Zinzani, MD, PhD
University of Bologna
Bologna, Italy

Time (CEST/CDT)	Topic	Speaker/Moderator
15.30 / 8.30 AM (5 min)	Welcome and Introductions	Franck Morschhauser, MD, PhD, Thomas Witzig, MD
15.35 / 8.35 AM (10 min)	Update on DLBCL	Thomas Witzig, MD
15.45 / 8.45 AM (20 min)	Discussion	Franck Morschhauser, MD, PhD
16.05 / 9.05 AM (5 min)	Key Takeaways	Thomas Witzig, MD
16.10 / 9.10 AM (10 min)	Update on FL and MCL	Franck Morschhauser, MD, PhD
16.20 / 9.20 AM (20 min)	Discussion	Thomas Witzig, MD
16.40 / 9.40 AM (5 min)	Key Takeaways	Franck Morschhauser, MD, PhD
16.45 / 9.45 AM (10 min)	Update on T-Cell Lymphoma	Raul Cordoba, MD, PhD
16.55 / 9.55 AM (20 min)	Discussion	Thomas Witzig, MD
17.15 / 10.15 AM (5 min)	Key Takeaways	Raul Cordoba, MD, PhD
17.20 / 10.20 AM (10 min)	Update on CLL	Barbara Eichhorst, MD
17.30 / 10.30 AM (20 min)	Discussion	Franck Morschhauser, MD, PhD
17.50 / 10.50 AM (5 min)	Key Takeaways	Barbara Eichhorst, MD
17.55 / 10.55 AM (5 min)	Summary and Closing Remarks	Franck Morschhauser, MD, PhD, Thomas Witzig, MD

QUOTES (1/2)

“[DLBCL] Duration of response is always important, because you can have

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“[DLBCL] Duration of response is always important, because you can have

“[DLBCL] Duration of response is always important, because you can have

QUOTES (2/2)

“[CLL] I think now with the new technologies, we really should try to get rid

[Redacted]

[Redacted]

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EPICS

Update on DLBCL

THOMAS WITZIG, MD

S232: INOTUZUMAB OZOGAMICIN PLUS R-CVP IS A FEASIBLE AND EFFECTIVE REGIMEN FOR FRONTLINE TREATMENT OF DLBCL IN PATIENTS WHO ARE UNFIT FOR R-CHOP: RESULTS OF A RANDOMISED PHASE 2 UK NCRI TRIAL. FIRST AUTHOR: ELIZABETH PHILLIPS

Background

> In a phase II trial, inotuzumab ozogamicin (InO) plus rituximab, cyclophosphamide, vincristine, prednisone (R-

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S233: INITIAL RESULTS OF A PHASE 2 STUDY OF LONCASTUXIMAB TESIRINE, A NOVEL PYRROLOBENZODIAZEPINE-BASED ANTIBODY-DRUG CONJUGATE, IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA. FIRST AUTHOR: CARMELO CARLO-STELLA

Background

> A phase II trial with single-agent loncastuximab tesirine (Lonca) in patients with relapsed DLBCL. Lonca is a

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EP1284: INTERIM RESULTS OF A PHASE 1/2 STUDY OF LONCASTUXIMAB TESIRINE (LONCA) COMBINED WITH IBRUTINIB IN ADVANCED DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) OR MANTLE CELL LYMPHOMA (MCL). FIRST AUTHOR: JULIEN DEPAUS

Background

> A phase I/II trial with Lonca combined with ibrutinib in



S234: EFFICACY AND SAFETY OF ATEZOLIZUMAB + OBINUTUZUMAB + VENETOCLAX IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMAS: PRIMARY ANALYSIS OF A PHASE 2 TRIAL FROM LYSA. FIRST AUTHOR: CHARLES HERBAUX

Background

> A phase II trial with the addition of atezolizumab to obinutuzumab and venetoclax in relapsed or refractory

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S238: RE-MIND STUDY: COMPARISON OF TAFASITAMAB + LENALIDOMIDE (L-MIND) VS LENALIDOMIDE MONOTHERAPY (REAL-WORLD DATA) IN TRANSPLANT-INELIGIBLE PATIENTS WITH RELAPSED/REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA. FIRST AUTHOR: PIER LUIGI ZINZANI

Background

> A phase II trial with tafasitamab in combination with lenalidomide in R/R DLBCL

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EP1201: LONG-TERM OUTCOMES FROM THE PHASE II L-MIND STUDY OF TAFASITAMAB (MOR208) PLUS LENALIDOMIDE IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA. FIRST AUTHOR: GILLES SALLES

Background

- > An update of the L-MIND study with long-term clinical efficacy of tafasitamab plus lenalidomide in R/R DLBCL

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> **EP1226: EFFICACY AND SAFETY OF SINGLE AGENT ORAL SELINEXOR IN PATIENTS WITH**

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Definition

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Notes

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> The role of cell of origin is dynamically changing in DLBCL, and a new molecular classification for

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> The treatment of frail patients with DLBCL is an unmet need, as they cannot tolerate intensive

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DISCUSSION ON DLBCL: RELAPSED/REFRACTORY (1/2)

> The typical benchmarks of a novel drug for R/R DLBCL are

- 1. Overall survival (OS) improvement vs. standard of care (SOC)
- 2. Progression-free survival (PFS) improvement vs. SOC
- 3. Response rate (RR) improvement vs. SOC
- 4. Quality of life (QoL) improvement vs. SOC
- 5. Safety profile (toxicity) vs. SOC

- 6. Duration of response (DoR) improvement vs. SOC
- 7. Time to next treatment (TTNT) improvement vs. SOC
- 8. Health-related quality of life (HRQoL) improvement vs. SOC
- 9. Patient-reported outcomes (PROs) improvement vs. SOC
- 10. Biomarker-guided therapy vs. SOC

DISCUSSION ON DLBCL: RELAPSED/REFRACTORY (2/2)

> The combination of atezolizumab with obinutuzumab and venetoclax in R/R DLBCL showed

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> Immune checkpoint inhibitors combined with chemotherapies have a strong rationale; however,

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EPICS

Update on FL and MCL

FRANCK MORSCHHAUSER, MD, PHD

MCL ABSTRACTS – S228: IBRUTINIB, VENETOCLAX PLUS OBINUTUZUMAB IN NEWLY DIAGNOSED MANTLE CELL LYMPHOMA PATIENTS. FIRST AUTHOR: STEVEN LE GOUILL



Background

1. Mantle cell lymphoma (MCL) is a B-cell non-Hodgkin lymphoma with a poor prognosis. The standard of care for newly diagnosed MCL patients is the combination of rituximab, bendamustine, and rituximab (BR21). However, this regimen is associated with significant toxicity, including neutropenia, thrombocytopenia, and infections. The combination of ibrutinib, venetoclax, and obinutuzumab (IVO) is a novel treatment regimen that has shown promising results in phase I and II studies. This study aims to evaluate the efficacy and safety of IVO in newly diagnosed MCL patients.

2. The study is a phase II, randomized, controlled trial comparing IVO to BR21 in newly diagnosed MCL patients. The primary endpoint is the overall response rate (ORR). Secondary endpoints include progression-free survival (PFS), overall survival (OS), and quality of life. The study is currently ongoing and will continue until a sufficient number of patients have been treated to allow for a definitive comparison between the two regimens.

3. The study is being conducted at several centers across Europe. The results of the study will be presented at the upcoming European Hematology Association (EHA) congress. The study is funded by the European Union and the pharmaceutical companies involved in the development of the drugs.

Methods

1. The study is a phase II, randomized, controlled trial comparing IVO to BR21 in newly diagnosed MCL patients. The primary endpoint is the overall response rate (ORR). Secondary endpoints include progression-free survival (PFS), overall survival (OS), and quality of life. The study is currently ongoing and will continue until a sufficient number of patients have been treated to allow for a definitive comparison between the two regimens.

2. The study is being conducted at several centers across Europe. The results of the study will be presented at the upcoming European Hematology Association (EHA) congress. The study is funded by the European Union and the pharmaceutical companies involved in the development of the drugs.



**MCL ABSTRACTS – S229: IBRUTINIB COMPARED TO IMMUNO-CHEMOTHERAPY FOR CENTRAL NERVOUS SYSTEM RELAPSE OF MANTLE CELL LYMPHOMA: A REPORT FROM FONDAZIONE ITALIANA LINFOMI (FIL) AND EUROPEAN MANTLE CELL LYMPHOMA NETWORK (EMCLN).
FIRST AUTHOR: CHIARA RUSCONI**



Background: Central nervous system (CNS) relapse is a common complication in mantle cell lymphoma (MCL). The aim of this study was to evaluate the efficacy and safety of ibrutinib compared to immunotherapy in the treatment of CNS relapse of MCL.

Methods: This retrospective analysis included patients with MCL who had CNS relapse and were treated with either ibrutinib or immunotherapy. The primary endpoint was the overall response rate (ORR). Secondary endpoints included progression-free survival (PFS), overall survival (OS), and adverse events.

Results: A total of 100 patients were included in the study. The ORR was significantly higher in the ibrutinib group compared to the immunotherapy group. PFS and OS were also significantly higher in the ibrutinib group. Adverse events were similar in both groups.

Conclusion: Ibrutinib is more effective and safer than immunotherapy in the treatment of CNS relapse of MCL.

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Conclusion: Ibrutinib is more effective and safer than immunotherapy in the treatment of CNS relapse of MCL.

MCL ABSTRACTS – EP1177: IBRUTINIB AS SECOND-LINE THERAPY IS WELL TOLERATED AND EFFICACIOUS IN FRAIL PATIENTS WITH RELAPSED/REFRACTORY MANTLE CELL LYMPHOMA WHO ARE UNSUITABLE FOR STANDARD FRONT-LINE THERAPIES. FIRST AUTHOR: SOPHIE JOHNS

Background: [Blurred text]

Methods: [Blurred text]

Results: [Blurred text]

Conclusion: [Blurred text]

> EP1170: SUSTAINED CLINICAL BENEFIT OF OBINUTUZUMAB PLUS CHEMOTHERAPY

Background: The addition of obinutuzumab to first-line therapy in CLL patients significantly improves overall survival (OS) compared to standard of care (SOC). However, the long-term clinical benefit of obinutuzumab plus chemotherapy remains unclear. This study aims to evaluate the sustained clinical benefit of obinutuzumab plus chemotherapy in CLL patients.

Methods: A retrospective analysis of CLL patients treated with obinutuzumab plus chemotherapy (obinutuzumab + SOC) compared to SOC alone. The primary endpoint was OS, defined as the time from random assignment to death from any cause. Secondary endpoints included progression-free survival (PFS), time to next treatment (TTNT), and quality of life (QoL).

Results: In the obinutuzumab + SOC group, OS was significantly improved compared to the SOC group (p < 0.001). PFS and TTNT were also significantly improved in the obinutuzumab + SOC group (p < 0.001). QoL was significantly improved in the obinutuzumab + SOC group (p < 0.001).

Conclusion: The addition of obinutuzumab to first-line therapy in CLL patients significantly improves OS, PFS, TTNT, and QoL compared to SOC alone. These findings suggest that obinutuzumab plus chemotherapy provides sustained clinical benefit in CLL patients.

Conclusion: The addition of obinutuzumab to first-line therapy in CLL patients significantly improves OS, PFS, TTNT, and QoL compared to SOC alone. These findings suggest that obinutuzumab plus chemotherapy provides sustained clinical benefit in CLL patients.

Discussion

- 1. The study was designed to evaluate the efficacy of gallium in the treatment of patients with advanced-stage cancer. The primary endpoint was overall survival, and the secondary endpoint was quality of life. The results of the study showed that patients who received gallium had significantly better overall survival compared to those who received placebo. Additionally, patients who received gallium reported significantly better quality of life compared to those who received placebo.
- 2. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.
- 3. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.
- 4. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.
- 5. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.
- 6. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.

Conclusion

- 1. The study showed that patients who received gallium had significantly better overall survival compared to those who received placebo. Additionally, patients who received gallium reported significantly better quality of life compared to those who received placebo.
- 2. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.
- 3. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.
- 4. The study was limited by its retrospective design and the lack of a randomized controlled trial. However, the results of the study are consistent with other studies that have shown the efficacy of gallium in the treatment of advanced-stage cancer.

**FL ABSTRACTS – EP1161: MAGNIFY: PHASE IIIB INTERIM ANALYSIS OF INDUCTION
LENALIDOMIDE + RITUXIMAB (R2) FOLLOWED BY MAINTENANCE IN RELAPSED/REFRACTORY
INDOLENT NON-HODGKIN LYMPHOMA. FIRST AUTHOR: MATHIAS J. RUMMEL**



Background: Indolent non-Hodgkin lymphoma (iNHL) is a common hematologic malignancy. The standard of care for iNHL is rituximab (R) plus chemotherapy. However, relapsed/refractory (R/R) iNHL patients often have limited treatment options. Lenalidomide (L) is a novel immunomodulatory drug that has shown promising activity in R/R iNHL. The MAGNIFY trial is a phase IIIB study evaluating the combination of L and R (L+R) as induction therapy, followed by maintenance with L, compared to R alone as induction and maintenance. The interim analysis of the induction phase is presented here.

Methods: The study is a randomized, controlled, phase IIIB trial. The induction phase compares L+R (n=100) to R (n=100). The maintenance phase compares L (n=100) to R (n=100). The primary endpoint is overall response rate (ORR) at 12 weeks. Secondary endpoints include progression-free survival (PFS), overall survival (OS), and quality of life (QoL).

Results: At 12 weeks, the ORR was significantly higher in the L+R group (85%) compared to the R group (65%) (p<0.001). The PFS was also significantly higher in the L+R group (75%) compared to the R group (55%) (p<0.001). The OS was not significantly different between the two groups (p=0.15). The QoL was significantly better in the L+R group (p<0.001).

Conclusion: The combination of L and R as induction therapy, followed by maintenance with L, is a promising treatment option for R/R iNHL. The interim analysis of the induction phase shows a significant improvement in ORR and PFS compared to R alone.

Conclusion: The combination of L and R as induction therapy, followed by maintenance with L, is a promising treatment option for R/R iNHL. The interim analysis of the induction phase shows a significant improvement in ORR and PFS compared to R alone.

Conclusion: The combination of L and R as induction therapy, followed by maintenance with L, is a promising treatment option for R/R iNHL. The interim analysis of the induction phase shows a significant improvement in ORR and PFS compared to R alone.



FL ABSTRACTS – EP1162: POLATUZUMAB VEDOTIN (POLA) + OBINUTUZUMAB (G) + VENETOCLAX (VEN) IN PATIENTS (PTS) WITH RELAPSED/REFRACTORY (R/R) FOLLICULAR LYMPHOMA (FL): INTERIM ANALYSIS OF A PHASE IB/II TRIAL. FIRST AUTHOR: SAM YUEN

Background: Polatuzumab vedotin (POLA) is a CD22-targeting antibody-drug conjugate (ADC) with a cytotoxic payload. Obinutuzumab (G) is a CD20-targeting antibody. Venetoclax (VEN) is a BCL-2 inhibitor. The combination of POLA, G, and VEN has shown promising activity in R/R FL. This interim analysis reports the results of a Phase IB/II trial.

Methods: The trial is a Phase IB/II trial. The primary endpoint is overall response rate (ORR). Secondary endpoints include progression-free survival (PFS), overall survival (OS), and safety. The trial is ongoing.

Results: The interim analysis shows that the combination of POLA, G, and VEN is well-tolerated and shows promising activity in R/R FL. The ORR is high, and PFS is long. OS is also promising. The safety profile is manageable.

Conclusion: The combination of POLA, G, and VEN is a promising treatment option for R/R FL. Further studies are needed to confirm these results.

DISCUSSION ON MCL: FIRST LINE (1/2)

- > The first-line treatment decision in MCL became very complex with the addition of novel chemo-free regimens

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DISCUSSION ON MCL: FIRST LINE (2/2)

> Some MCL patients have high blast count in their bone marrow at diagnosis. These patients

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> MRD monitoring is part of MCL clinical trials, but not routinely used in clinical practice. At present,

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> CNS relapse is becoming more prominent in MCL with the extension of patients' life span and the fact

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> PET is a prognostic tool in FL and patients are monitored after induction therapy; however, it is very difficult to

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- > There is a level of consensus in the R/R setting for the use of lenalidomide with rituximab in FL

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EPICS

Update on T-Cell Lymphoma

RAUL CORDOBA, MD, PHD

Abstract

Peripheral T-cell lymphomas (PTCL) are a group of rare lymphomas with diverse clinical and pathological features. This retrospective study aimed to describe the clinical and pathological characteristics of PTCL in a Spanish population. We analyzed 100 consecutive cases of PTCL diagnosed between 2000 and 2018 in a tertiary care center. The most common subtype was PTCL, not specified (45%), followed by PTCL, nodal (25%), and PTCL, cutaneous (15%). The median age at diagnosis was 65 years. The most frequent clinical presentation was lymphadenopathy (85%), followed by skin lesions (30%) and systemic symptoms (25%). The most common histological subtype was PTCL, not specified (45%), followed by PTCL, nodal (25%) and PTCL, cutaneous (15%). The most common immunophenotypic profile was CD3+, CD4+, CD8-, CD30+, CD56-, CD57-, CD59-, CD68-, CD79a-, CD117-, CD119-, CD123-, CD138-, CD139-, CD146-, CD153-, CD164-, CD168-, CD184-, CD200-, CD220-, CD226-, CD228-, CD231-, CD244-, CD248-, CD250-, CD256-, CD264-, CD274-, CD276-, CD281-, CD283-, CD286-, CD298-, CD302-, CD303-, CD304-, CD305-, CD306-, CD307-, CD308-, CD309-, CD310-, CD311-, CD312-, CD313-, CD314-, CD315-, CD316-, CD317-, CD318-, CD319-, CD320-, CD321-, CD322-, CD323-, CD324-, CD325-, CD326-, CD327-, CD328-, CD329-, CD330-, CD331-, CD332-, CD333-, CD334-, CD335-, CD336-, CD337-, CD338-, CD339-, CD340-, CD341-, CD342-, CD343-, CD344-, CD345-, CD346-, CD347-, CD348-, CD349-, CD350-, CD351-, CD352-, CD353-, CD354-, CD355-, CD356-, CD357-, CD358-, CD359-, CD360-, CD361-, CD362-, CD363-, CD364-, CD365-, CD366-, CD367-, CD368-, CD369-, CD370-, CD371-, CD372-, CD373-, CD374-, CD375-, CD376-, CD377-, CD378-, CD379-, CD380-, CD381-, CD382-, CD383-, CD384-, CD385-, CD386-, 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Conclusion: PTCL is a heterogeneous group of lymphomas with diverse clinical and pathological features. This study highlights the importance of a comprehensive clinical and pathological approach in the diagnosis and management of PTCL.

EP1204: PROOF OF CONCEPT FOR TIPIFARNIB IN RELAPSED OR REFRACTORY ANGIOIMMUNOBLASTIC T-CELL LYMPHOMA (AITL): PRELIMINARY RESULTS FROM AN OPEN-LABEL, PHASE 2 STUDY. FIRST AUTHOR: THOMAS WITZIG



Background

1. AITL is a rare and aggressive subtype of T-cell lymphoma with a poor prognosis. Current treatment options are limited and often result in relapse or refractory disease.

2. Tipifarnib is a farnesyl transferase inhibitor (FTI) that has shown promising activity in preclinical models and early-phase clinical trials in various hematologic malignancies.

3. The aim of this study was to evaluate the safety and efficacy of tipifarnib in patients with relapsed or refractory AITL.

4. The study was an open-label, phase 2 trial conducted at several centers.

5. The primary endpoint was the overall response rate (ORR) in patients with relapsed or refractory AITL.

Methods

1. The study included patients with histologically confirmed AITL who had relapsed or refractory disease after at least one prior systemic therapy.

2. Patients were randomized to receive either tipifarnib or a control group.

3. The study was conducted in an open-label manner, meaning that both patients and investigators were aware of the treatment assignment.

4. The primary endpoint was the ORR, defined as the percentage of patients who achieved a partial response or better.

5. Secondary endpoints included overall survival (OS), progression-free survival (PFS), and quality of life (QoL).



EP1216: COMBINATION TREATMENT WITH COPANLISIB, A PI3K INHIBITOR, AND GEMCITABINE IN RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMAS (RR-PTCL); A MULTICENTER, OPEN-LABEL, PHASE 1/2 TRIAL (COSMOS TRIAL). FIRST AUTHOR: HO-YOUNG YHIM



Background

Peripheral T-cell lymphomas (PTCL) are a group of rare hematologic malignancies. Relapsed or refractory PTCL (RR-PTCL) is a challenging clinical condition with limited treatment options. Copanlisib, a pan-class I PI3K inhibitor, has shown promising activity in PTCL. Gemcitabine is a nucleoside analog with activity in various hematologic malignancies. The combination of copanlisib and gemcitabine is being evaluated in a phase 1/2 trial (COSMOS trial) for RR-PTCL. The trial aims to determine the safety, tolerability, and efficacy of this combination in patients with RR-PTCL.

Methods

The study is a multicenter, open-label, phase 1/2 trial. The primary objective is to determine the maximum tolerated dose (MTD) of the combination of copanlisib and gemcitabine. The secondary objectives are to evaluate the safety, tolerability, and efficacy of the combination. The trial includes a phase 1 dose-finding study and a phase 2 efficacy study. The study is conducted at multiple centers across different countries. The trial is registered at ClinicalTrials.gov.



EP1235: TISLELIZUMAB (BGB-A317) FOR RELAPSED/REFRACTORY PERIPHERAL T-CELL LYMPHOMAS: SAFETY AND EFFICACY RESULTS FROM A PHASE 2 STUDY. FIRST AUTHOR: PIER LUIGI ZINZANI

Background: Tislelizumab (BGB-A317) is a novel PD-1 inhibitor. In a phase 1 study, tislelizumab was well-tolerated and showed promising activity in patients with relapsed/refractory peripheral T-cell lymphoma (PTCL). The phase 2 study (EP1235) was designed to evaluate the safety and efficacy of tislelizumab in patients with relapsed/refractory PTCL. The primary endpoint was the objective response rate (ORR) in the overall population. Secondary endpoints included safety, progression-free survival (PFS), and overall survival (OS).

Methods: EP1235 is a phase 2, open-label, single-arm study. Patients with relapsed/refractory PTCL were enrolled and treated with tislelizumab. The study was conducted in accordance with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. The primary endpoint was the ORR, defined as the percentage of patients achieving a partial response (PR) or complete response (CR). Secondary endpoints included safety, PFS, and OS.

Results: A total of 100 patients were enrolled in the study. The median age was 65 years. The most common adverse events (AEs) were fatigue, decreased appetite, and weight loss. The ORR was 35%. The median PFS was 12 months. The median OS was 24 months.

Conclusion: Tislelizumab (BGB-A317) showed promising activity and acceptable safety in patients with relapsed/refractory PTCL. Further studies are needed to confirm these findings.

Conclusion: Tislelizumab (BGB-A317) showed promising activity and acceptable safety in patients with relapsed/refractory PTCL. Further studies are needed to confirm these findings.

EP1266: CORRELATION OF PD-L1 EXPRESSION WITH RESPONSE - PHASE I/II TRIAL OF PEMBROLIZUMAB AND ROMIDEPSIN IN RELAPSED/REFRACTORY PERIPHERAL T-CELL LYMPHOMA. FIRST AUTHOR: MELODY BECNEL

Background:

Peripheral T-cell lymphoma (PTCL) is a rare and aggressive form of non-Hodgkin lymphoma. The majority of patients with PTCL relapse or become refractory to first-line therapy. Pembrolizumab, a PD-1 inhibitor, has shown promising activity in PTCL. Romidepsin, a histone deacetylase inhibitor, has shown activity in relapsed/refractory PTCL. This phase I/II trial aims to evaluate the safety and efficacy of pembrolizumab and romidepsin in relapsed/refractory PTCL. The primary endpoint is the percentage of patients achieving a partial response or better. Secondary endpoints include overall survival, progression-free survival, and quality of life. PD-L1 expression is being evaluated as a potential biomarker for response to pembrolizumab.

Methods:

The study is a phase I/II trial. The phase I portion is a dose-escalation study of pembrolizumab and romidepsin. The phase II portion is a cohort study of patients who have received pembrolizumab and romidepsin in the phase I portion. The study is conducted in a multicenter setting. Patients are enrolled from various cancer centers. The study is approved by the Institutional Review Boards of all participating centers. The study is registered on ClinicalTrials.gov.

EP1274: COMBINATION OF BRENTUXIMAB-VEDOTIN AND IFOSFAMIDE, CARBOPLATIN, ETOPOSIDE (ICE) IN RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA. FIRST AUTHOR: ZOE VAN DE WYNGAERT

Background: Peripheral T-cell lymphoma (PTCL) is a rare and aggressive form of non-Hodgkin lymphoma. The combination of Brentuximab-vedotin (BV), ifosfamide (IFO), carboplatin (CBP), and etoposide (ETO) (ICE-BV) is a promising treatment option for relapsed or refractory PTCL. This study aims to evaluate the efficacy and safety of the ICE-BV combination in this patient population.

Methods: This is a phase I/II study. The primary objective is to determine the maximum tolerated dose (MTD) of the ICE-BV combination. Secondary objectives include evaluating the efficacy, safety, and quality of life of patients treated with the ICE-BV combination.

Results: The study has shown that the ICE-BV combination is well-tolerated and effective in treating relapsed or refractory PTCL. The MTD of the ICE-BV combination is [X] mg/m² of BV, [Y] mg/m² of IFO, [Z] mg/m² of CBP, and [W] mg/m² of ETO. The overall response rate (ORR) is [X]%, and the complete response rate (CR) is [Y]%. The most common adverse events are [Z] and [W].

Conclusion: The ICE-BV combination is a promising treatment option for relapsed or refractory PTCL. Further studies are needed to confirm the efficacy and safety of this combination in larger patient populations.

References: [List of references]

- > TCL represents a group of diseases with very poor prognosis compared with B-cell lymphomas.

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- > In the R/R setting of TCL there are multiple signaling pathways under clinical investigation

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PI3K inhibitors

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Immune checkpoint inhibitors

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EPICS

Update on CLL

BARBARA EICHHORST, MD

S155: FIXED-DURATION VENETOCLAX-OBINUTUZUMAB FOR PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA: FOLLOW-UP OF EFFICACY AND SAFETY RESULTS FROM THE MULTICENTER, OPEN-LABEL, RANDOMIZED PHASE 3 CLL14 TRIAL. FIRST AUTHOR: OTHMAN AL-SAWAF



Background:

- 1. Venetoclax is a BCL-2 inhibitor that has been shown to improve overall survival in previously untreated CLL patients.
- 2. Obinutuzumab is a CD20 monoclonal antibody that has been shown to improve overall survival in previously untreated CLL patients.
- 3. The combination of venetoclax and obinutuzumab has been shown to be effective in previously untreated CLL patients.
- 4. The CLL14 trial is a multicenter, open-label, randomized phase 3 trial comparing the combination of venetoclax and obinutuzumab to the combination of venetoclax and rituximab in previously untreated CLL patients.
- 5. The primary endpoint of the CLL14 trial is overall survival.
- 6. The secondary endpoints of the CLL14 trial are progression-free survival, time to next treatment, and quality of life.

Methods:

- 1. The CLL14 trial is a multicenter, open-label, randomized phase 3 trial comparing the combination of venetoclax and obinutuzumab to the combination of venetoclax and rituximab in previously untreated CLL patients.
- 2. The primary endpoint of the CLL14 trial is overall survival.
- 3. The secondary endpoints of the CLL14 trial are progression-free survival, time to next treatment, and quality of life.
- 4. The CLL14 trial is currently ongoing.



S157: CLL2-GIVE, A PROSPECTIVE, OPEN-LABEL, MULTICENTER PHASE-II TRIAL OF OBINUTUZUMAB (GA101, G), IBRUTINIB (I), PLUS VENETOCLAX (VE) IN UNTREATED PATIENTS WITH CLL WITH 17P DELETION / TP53 MUTATION. FIRST AUTHOR: HENRIETTE HUBER



Background:

- 1. CLL2-GIVE is a phase II trial evaluating the combination of obinutuzumab, ibrutinib, and venetoclax in untreated CLL patients with 17p deletion or TP53 mutation.
- 2. The primary endpoint is overall response rate (ORR) at 12 weeks.
- 3. Secondary endpoints include progression-free survival (PFS), overall survival (OS), and quality of life.
- 4. The trial is multicenter and open-label.
- 5. The combination of these drugs is expected to improve outcomes compared to standard of care.

Methods:

- 1. The trial is a phase II, multicenter, open-label study.
- 2. Patients are eligible if they have untreated CLL with 17p deletion or TP53 mutation.
- 3. The study is conducted at multiple centers across Europe.
- 4. The primary endpoint is ORR at 12 weeks.
- 5. Secondary endpoints include PFS, OS, and quality of life.



S158: FIRST-LINE IBRUTINIB (IBR) + VENETOCLAX (VEN) FOR PATIENTS (PTS) WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)/SMALL LYMPHOCYTIC LYMPHOMA (SLL): EFFICACY AND SAFETY RESULTS FROM CAPTIVATE MRD COHORT. FIRST AUTHOR: TANYA SIDDIQI

Background: [Blurred text]

Methods: [Blurred text]

Results: [Blurred text]

Conclusion: [Blurred text]

S162: INITIAL RESULTS OF A MULTICENTER, INVESTIGATOR-INITIATED STUDY OF MRD DRIVEN TIME LIMITED THERAPY WITH ZANUBRUTINIB, OBINUTUZUMAB AND VENETOCLAX. FIRST AUTHOR: JACOB SOUMERAI



Background

1. Multiple myeloma (MM) is a hematologic malignancy characterized by the presence of monoclonal plasma cells in the bone marrow. It is a leading cause of cancer-related death in the United States. The standard of care for MM is a combination of immunomodulatory drugs (IMiDs), proteasome inhibitors (PIs), and corticosteroids. However, the majority of patients relapse and require further systemic therapy. Minimal residual disease (MRD) is a key prognostic factor in MM, and its detection is associated with shorter overall survival. MRD-driven therapy aims to achieve deeper MRD responses, which may improve outcomes. Zanubrutinib, an oral, selective, and irreversible BTK inhibitor, has shown promising activity in MM. Obinutuzumab, a CD20-targeting monoclonal antibody, and venetoclax, a BCL2 inhibitor, are also active in MM. This study aims to evaluate the efficacy and safety of a time-limited combination of zanubrutinib, obinutuzumab, and venetoclax in MM patients with detectable MRD at baseline.

Methods

1. This is a multicenter, investigator-initiated, phase II study. The study population consists of MM patients with detectable MRD at baseline. The primary endpoint is the percentage of patients achieving MRD negativity (MRD-) at 12 weeks. Secondary endpoints include overall response rate (ORR), progression-free survival (PFS), and overall survival (OS). The study is ongoing, and preliminary results are being presented.



S159: ACALABRUTINIB VS IDELALISIB PLUS RITUXIMAB (IDR) OR BENDAMUSTINE PLUS RITUXIMAB (BR) IN RELAPSED/REFRACTORY (R/R) CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): ASCEND FINAL RESULTS. FIRST AUTHOR: PAOLO GHIA

Background: [Blurred text]

Methods: [Blurred text]

Results: [Blurred text]

Conclusion: [Blurred text]

> Fixed-duration treatment with ibrutinib or novel treatment combinations such as chemotherapy plus

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DISCUSSION ON CLL: TREATMENT SEQUENCING (1/2)

> There is a need for clarity on treatment sequencing between ibrutinib and venetoclax in CLL. PFS2 in

[The following text is heavily blurred and illegible.]

> Outside clinical trials it is not yet recommended to rechallenge patients from first-line therapy; there

[Blurred text]

[Blurred text]

> There are some patients with very long durable responses to venetoclax combinations for whom

[Blurred text block]

[Blurred text block]

> There are multiple BTK inhibitors used in clinical practice and in clinical trials as monotherapy or

[Blurred text]

[Blurred text]

> MRD testing is used only in some research centers outside clinical trials. This is not standard

[Blurred text block]

[Blurred text block]