CML AdvocatesNetwork

ASH 2021

CML ADVOCATES NETWORK CONFERENCE REPORT

63rd ASH Annual Meeting and Exposition

DECEMBER 11-14, 2021
ATLANTA, GA
IN-PERSON/VIRTUAL

63rd American Society of Hematology Congress

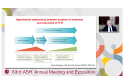
The **63rd ASH Annual Meeting and Exposition** organised by the **American Society of Hematology** was presented at the Georgia World Congress Center in Atlanta, Georgia – and virtually – from December 11-14, 2021.

This report summarizes the Chronic Myeloid Leukemia highlights presented in this key meeting for the global CML patient advocacy community:

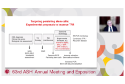
- Education Program: CML: Success Breeds More Success.
- 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Mechanisms of Resistance and Expanded Therapies.
- 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Progress with Response Prediction and TKI Discontinuation.
- Other Abstracts and Posters
- Special Symposium on Quality: Identifying and Eliminating Inequity in the Provision of Healthcare.
- The Role of Real World Data Collection in Hematologic Malignancies.
- ASH Advances COVID Research 2021.

CML EDUCATION PROGRAM

TKI Discontinuation: How to Make More Patients Eligible? How to Increase the Chances of a Successful Treatment-Free Remission? Andreas Hochhaus, M.D.


Hypothetical relationship between duration of treatment and outcomes of TFR

63rd ASH Annual Meeting and Exposition


Targeting persisting stem cells: Experimental proposals to improve TFR

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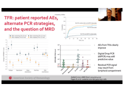
This first session of the education program was focused on requirements for TKI discontinuation published at the **ELN Recommendations 2020** and the most recent updates on treatment-free remission.

Dr. Hochhaus discussed about TFR after stop of 1st and 2nd generation TKI, TFR legibility, hypothetical relationship between duration of treatment and outcomes of TFR, monitoring on genomic level, leukemia immunoediting in CML and experimental proposals to improve TFR among other topics.
He concluded that a significant proportion of CML patients achieve DMR with TKI therapy. Speed of response is faster under treatment with 2nd generation inhibitors than with imatinib.

Life-Long TKI Therapy: How to Manage Cardiovascular and Other Risks. Michael Mauro, M.D.


TFR: patient reported AEs, alternate PCR strategies, and the question of MRD

AEs from TKIs clearly improve
Digital Drop PCR (ddPCR) may add predictive value
Residual PCR signal may result from lymphoid compartment

Guidelines in active development for CML patients and CV risk

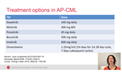
The second session run by Dr. Mauro was through the knowledge on different topics:

- Expanding therapeutic landscape in CML.
- Initial decision point-disease risk and front-line therapy associated risk.
- Risk assessment on cardiovascular disease: who, when and how?
- TFR and CML survivorship finishing with the following question: Is CML therapy indeed necessary life-long?

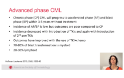
Conclusions are:

- Typical patient afflicted with CML has comorbid conditions and/or comorbidity risks.
- Continued optimization of CML therapy is about how many TKIs and how we best use them.
- Treatment free remission may be the goal for all.

Blast and Accelerated Phase CML: Room for Improvement. Gabriela Hobbs, M.D.


Treatment options in AP-CML

TKI	Dose
Dasatinib	140 mg daily
Nilotinib	400 mg BID
Ponatinib	45 mg daily
Bosutinib	500 mg daily
Imatinib	600 mg daily
Omacetaxine	1.25mg/m2 (14 days for 1st 28 day cycle, 7 days subsequent cycles)


Advanced phase CML

- Chronic phase (CP) CML will progress to accelerated phase (AP) and blast phase (BP) within 3-5 years without treatment
- Incidence of AP/BP is low, but outcomes are poor compared to CP
- Incidence decreased with introduction of TKIs and again with introduction of 2nd gen TKIs
- Outcomes have improved with the use of TKI+chemo
- 70-80% of blast transformation is myeloid
- 20-30% lymphoid

At the third talk of the session, Dr. Hobbs presented information focused on the accelerated phase of CML, highlighting interesting points as the followings:

CML clonal evolution; definitions and requirements of accelerated phase (AP) and blast phase (BP); treatment options in this phase; risk stratification and transplantation in advanced CML.

Conclusions:

- Outcome of AP and BP remains poor.
- Standard treatment for AP and BP are lacking.
- Improved risks stratification systems are needed.
- Transplantation is the only curative therapy.

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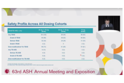
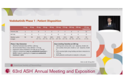
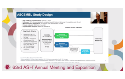
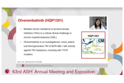
632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Mechanisms of Resistance and Expanded Therapies.


Safety Profile Across All Dosing Cohorts

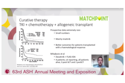
Responses and Outcomes by ABL Mutation Status


Vodobatinib Phase 1 : Patient Disposition


ASCEMBL Study Design


Olverembatinib (HQP1351)

- Mutation-driven resistance to tyrosine kinase inhibitors (TKIs) is a critical clinical challenge in chronic myeloid leukemia (CML).
- Olverembatinib is an investigational, novel, potent, oral third-generation TKI of BCR-ABL1 with activity against TKI resistance, including with T315I mutation.


Curative therapy
TKI + chemotherapy + allogeneic transplant

This Oral and Poster Abstract session was moderated by Susan Branford PhD and Michael J. Mauro MD, and included very interesting presentations as follows:

- **307.** Post Hoc Analysis of Responses to Ponatinib in Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) By Baseline BCR-ABL1 Level and Baseline Mutation Status in the Optic TrialClinically Relevant Abstract. Michael W. Deininger, MD, PhD.
- **308.** Correlations between Mutations in Cancer-Related Genes, Therapy Responses and Outcomes of the 3rd Generation Tyrosine Kinase-Inhibitor (TKI) in Persons with Chronic Myeloid Leukemia Failing Prior TKI-TherapyClinically Relevant Abstract. Xiaoshuai Zhang.
- **309.** An Update of Safety and Efficacy Results from Phase 1 Dose-Escalation and Expansion Study of Vodobatinib, a Novel Oral BCR-ABL1 Tyrosine Kinase Inhibitor (TKI), in Patients with Chronic Myeloid Leukemia (CML) and Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL) Failing Prior TKI Therapies. Jorge E. Cortes, MD.
- **310.** Efficacy and Safety Results from Ascembl, a Multicenter, Open-Label, Phase 3 Study of Asciminib, a First-in-Class STAMP Inhibitor, Vs Bosutinib in Patients with Chronic Myeloid Leukemia in Chronic Phaseafter ≥2 Prior Tyrosine Kinase Inhibitors: Update after 48 WeeksClinically Relevant Abstract. Michael J. Mauro, MD.
- **311.** Updated Safety and Efficacy Results of Phase 1 Study of Olverembatinib (HQP1351), a Novel Third-Generation BCR-ABL Tyrosine Kinase Inhibitor (TKI), in Patients with TKI-Resistant Chronic Myeloid Leukemia (CML)Clinically Relevant Abstract. Jiang Qian, MD.
- **312.** Ponatinib in Combination with FLAG-IDA Chemotherapy for Blast-Phase Chronic Myeloid Leukemia: Final Results of the Seamless Phase I/II Dose-Finding UK Trials Acceleration Programme (TAP) Matchpoint Trial. Mhairi Copland, PhD, MBBChir, FRCP, FRCPath.

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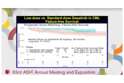
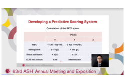
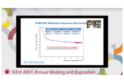
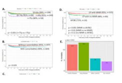
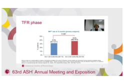
632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Progress with response prediction and TKI discontinuation.

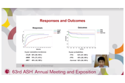

Low-dose vs. Standard-dose Dasatinib in CML
Failure-free Survival


Developing a Predictive Scoring System


EURO-SKI: Molecular recurrence-free survival



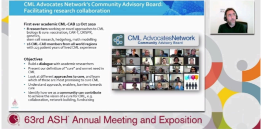

TFR phase


Responses and Outcomes

Oral and Poster Abstract session moderated by Jorge E. Cortes MD and Mhairi Copland PhD, MBBChir, FRCP, FRCPath, including an overview of the following studies:

- **631.** Low-Dose Dasatinib 50 Mg/Day Versus Standard-Dose Dasatinib 100 Mg/Day As Frontline Therapy in Chronic Myeloid Leukemia in Chronic Phase: A Propensity Score Analysis. Koji Sasaki, MD, PhD
- **632.** A Predictive Score for Failure-Free Survival in Persons with Chronic Myeloid Leukemia Receiving Imatinib. Xiaoshuai Zhang
- **633.** FINAL Analysis of a PAN European STOP Tyrosine Kinase Inhibitor Trial in Chronic Myeloid Leukemia : The EURO-SKI StudyClinically Relevant Abstract. Francois-Xavier Mahon, MD, PhD
- **634.** COVID-19 in Patients with Chronic Myeloid Leukemia: Poor Outcomes for Patients with Comorbidities, Older Age, Advanced Phase Disease, and Those from Low-Income Countries: An Update of the Candid Study. Katia B Pagnano, MD, PhD
- **635.** Treatment-Free Remission (TFR) after Two Different Durations of Nilotinib Consolidation in Patients with Chronic Myeloid Leukemia (CML) Previously Treated with Imatinib: Enestpath Study Results. Delphine Rea, MD, PhD
- **636.** A Predictive Score for Outcomes of Tyrosine Kinase-Inhibitor Therapy in Persons with Chronic Myeloid Leukaemia Presenting in Accelerated Phase. Sen Yang, MD.

Special-Interest Sessions


CML Advocates Network's Community Advisory Board: Facilitating research collaboration

First ever academic CML-CAB 12 Oct 2020
- **8 researchers** working on novel approaches to CML biology & cure: vaccination, CAR-T, CRISPR, genetics, stem cell research, hedgehog, math modelling
- **16 CML-CAB members from all world regions** with 223 patient years of lived CML experience

Objectives
- Build a **dialogue** with academic researchers
- Present our definition of "cure" and unmet need in CML
- Look at different **approaches to cure,** and learn which of these are most promising to cure CML
- Understand approach, enablers, barriers towards cure
- Identify how we as a **community can contribute** to achieve the vision of a cure for CML, e.g. collaboration, network building, fundraising

CML AdvocatesNetwork
Community Advisory Board

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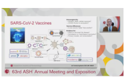
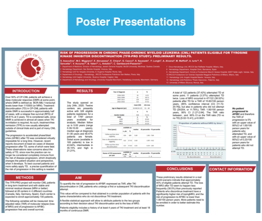
Health Disparities are Real

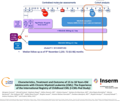

SARS-CoV-2 Vaccines

Our summary provides you with some special-interest sessions like:

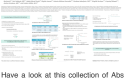
- **"The Role of Real World Data Collection in Hematologic Malignancies"**, with the participation of our co-founder **Jan Geissler** presenting **"Patient's Viewpoint on Real World Data Sharing"** to address the importance of real-world evidence and patient experience data to reflect patient reality beyond clinical reality.
- **Special Symposium on Quality: "Identifying and Eliminating Inequity in the Provision of Healthcare."** including the following talks **"Mechanisms for Change in Health Equity; "Equity in Patient Care and Outcomes";The Social and Moral Determinants of Health / Equity in Healthcare."**
- **ASH Advances COVID Research 2021**, discussing about **"Immunology and Immune Response to COVID-19 Vaccines"; "Thrombosis in the Setting of COVID-19"** and **"Outcomes of COVID-19 Infection in Hematology Patients."**

Poster Presentations


RISK OF PROGRESSION IN CHRONIC PHASE-CHRONIC MYELOID LEUKEMIA (CML) PATIENTS ELIGIBLE FOR TYROSINE KINASE INHIBITOR DISCONTINUATION (TFR-PRO STUDY): PRELIMINARY RESULTS.


PETALs trial current follow-up

MUTATIONAL PROFILES DURING THE PROGRESSION OF CHRONIC MYELOID LEUKEMIA


Characteristics, Treatment and Outcome of 15 to 18 Years-Old Adolescents with Chronic Myeloid Leukemia (CML): The Experience of the International Registry of Childhood CML (I-CML-Ped Study)

Efficacy and Safety of Generic Dasatinib as First-line Treatment in patients with chronic myeloid leukemia in Chronic Phase: Final Analysis with 2-year Follow-up

Have a look at this collection of Abstracts and Poster presentations we have selected for you:

- **1476** Risk of Progression in Chronic Phase - Chronic Myeloid Leukemia (CML) Patients Eligible for Tyrosine Kinase Inhibitor Discontinuation (TFR-PRO study): Preliminary Results. Sarit Assouline, MD.
- **2553** Treatment-Free Remissions in Newly Diagnosed CP CML Patients Treated with the Combination of Nilotinib + Pegylated Interferon Alpha 2a Versus Nilotinib Alone in the National Phase III Petals Trial. Franck Nicolini, MD,PhD.
- **3596** Mutational Profiles during the Progression of Chronic Myeloid Leukemia. Mengxing Xue.
- **3602** Characteristics, Treatment and Outcome of 15 to 18 Years-Old Adolescents with Chronic Myeloid Leukemia (CML): The Experience of the International Registry of Childhood CML (I-CML-Ped Study). Morgane Froment.
- **3616** Efficacy and Safety of Generic Dasatinib As First-Line Treatment in Patients with Chronic Myeloid Leukemia in Chronic Phase: Final Analysis with 2-Year Follow-up. Jie Jin, MD, PhD.

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