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CLL: Update on Treatment and Side Effects Management

John C. Byrd, MD
*D. Warren Brown Chair of Leukemia Research
Professor of Medicine, Medicinal Chemistry and Veterinary Biosciences
Director, Division of Hematology, Department of Medicine
The Ohio State University
Columbus, OH*

Kimberly A. Holt, BSN, RN, OCN®
*Patient Care Resource Manager
James Cancer Hospital and Solove Research Institute
Columbus, OH*

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CLL: Update on Treatment and Side Effects Management

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Welcome and Introductions

CLL: Update on Treatment and Side Effects Management



Disclosures

John C. Byrd, MD does not have any relevant financial relationships with any commercial interests to disclose.

Kimberly A. Holt, BSN, RN, OCN® does not have any relevant financial relationships with any commercial interests to disclose.

Current CLL Therapy Landscape 2015

John C. Byrd M.D.
D. Warren Brown Chair of Leukemia Research
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Director, Division of Hematology
The Ohio State University

The Ohio State University Comprehensive Cancer Center –
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Chronic Lymphocytic Leukemia

- The most prevalent type of adult leukemia
- Defined by $< 5 \times 10^9/L$ CD5, CD19, CD20, CD23, slg (dim)+ cells in blood
- $< 5 \times 10^9/L$ cells in blood without cytopenias or organomegaly is monoclonal B-cell lymphocytosis (MBL) with many of the same complications and 1-2% chance of progression to CLL/per year
- Median age of diagnosis of CLL is approximately 72, with only 10% of patients under age 50.
- More common in men than women (2:1 ratio)
- Environmental predisposition uncertain, although Vietnam Veterans with Agent Orange exposure warrant “service-connected status”
- Genetic predisposition present, with approximately 10% of patients having a first-generation relative with CLL—no common gene

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Initial Work-up of CLL Patients

- All patients at diagnosis:
 - « Flow cytometry to confirm CLL diagnosis
- Informative for prognostic and/or therapy determination
 - « Interphase cytogenetics looking for +12, del(13q), del(17)(p13.1) and del(11)(q22.3); del 17p and del 11q portend for more aggressive disease
 - « Unmutated V_H gene status assessment (good lab)
 - « ZAP-70 expression by flow cytometry is not recommended outside clinical trial
 - « Beta-2-microglobulin
- No CT scan unless symptoms are present; PET scan can be helpful if Richter’s suspected
- Bone marrow biopsy and aspirate not necessary in absence of cytopenias

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Complications of CLL

- Infections
- Autoimmune complications
- Secondary cancers
- Richter's transformation

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When to Treat CLL Patients

- No advantage to treating CLL until symptoms develop irrespective of genomic features
- IWCLL 2008 criteria for treatment (primary and in relapse include
 - Enlarging, symptomatic lymph nodes (> 10 cm)
 - Enlarging, symptomatic spleen (> 6 cm)
 - Cytopenias due to CLL (hemoglobin < 11, platelets < 100)
 - Constitutional symptoms due to disease (fatigue, B-symptoms)
 - Poorly controlled AIHA or ITP
- Lymphocyte count < 300 x 10⁹/L or doubling time not an indication for Rx *

Hallek M, et al. *Blood* 15:5446-56, 2008
*NCCN Guidelines for NHL 2014

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How to Differentiate Patients for Treatment

- Age or Functional Status
 - Age 65-70 often used in US
 - CIRS score or creatinine clearance < 60 ml/min often used in Europe

- Genomic Features
 - Del(17p13.1) or not
 - Favorable markers (IgHV mutated with del(13q14) or +12)

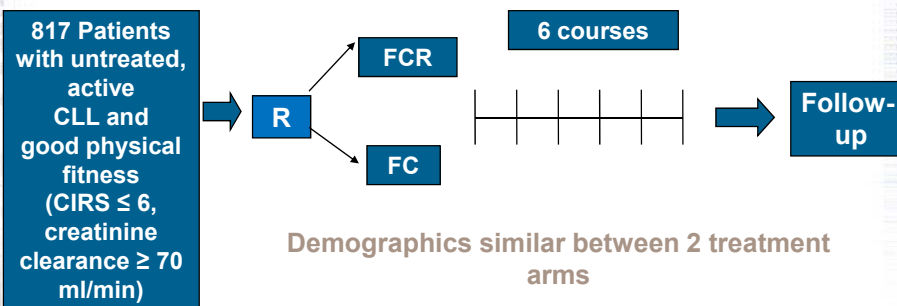
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CLL8 Study Design



Updated results of the 3rd analysis
Median observation time 5.9 years

Hallek M, et al: *Lancet*. 376:1164, 2010, Updated ASH 2012

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Summary of German CLL8 Study

- Toxicity of FCR similar to FC except for more neutropenia
- FCR versus FC a better therapy for young CLL
 - Significantly improves ORR and CR
 - Significantly improves PFS (57 versus 33 months, at 5.9 yrs)
 - Significantly improves OS (69.2% vs 62.3% at 5.9 yrs)
- MRD status at end of therapy most predictive factor for long term PFS and OS
- Majority of genetic groups benefit from FCR therapy except for
 - Del(17p13.1)
 - Normal karyotype (using FISH probes only)

Hallek M, et al: *Lancet*. 376:1164, 2010

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Recent Data to Consider Decisions

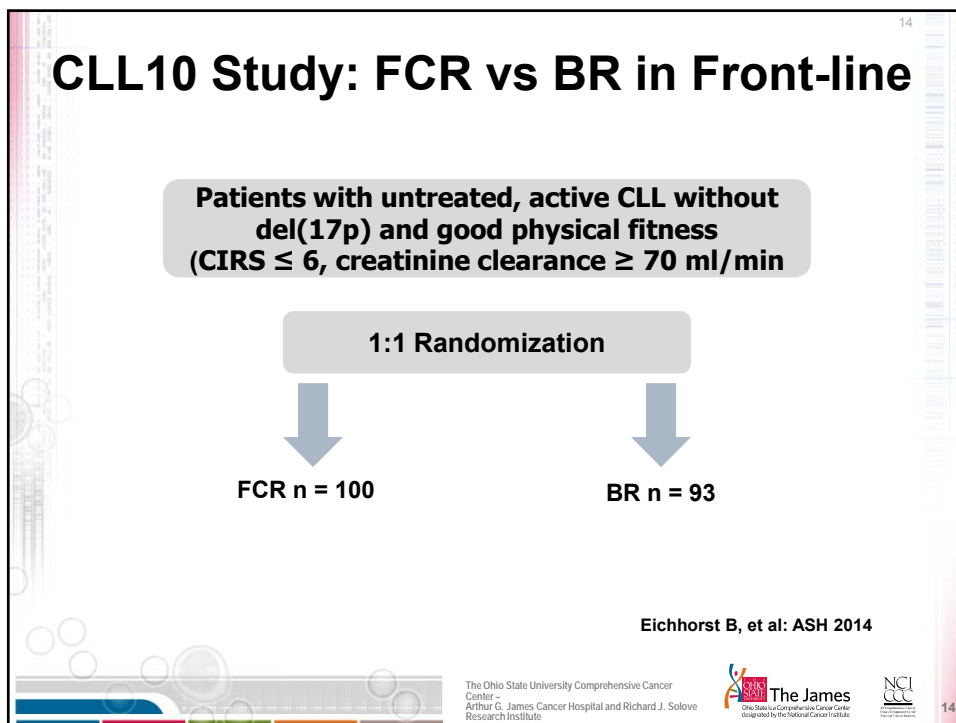
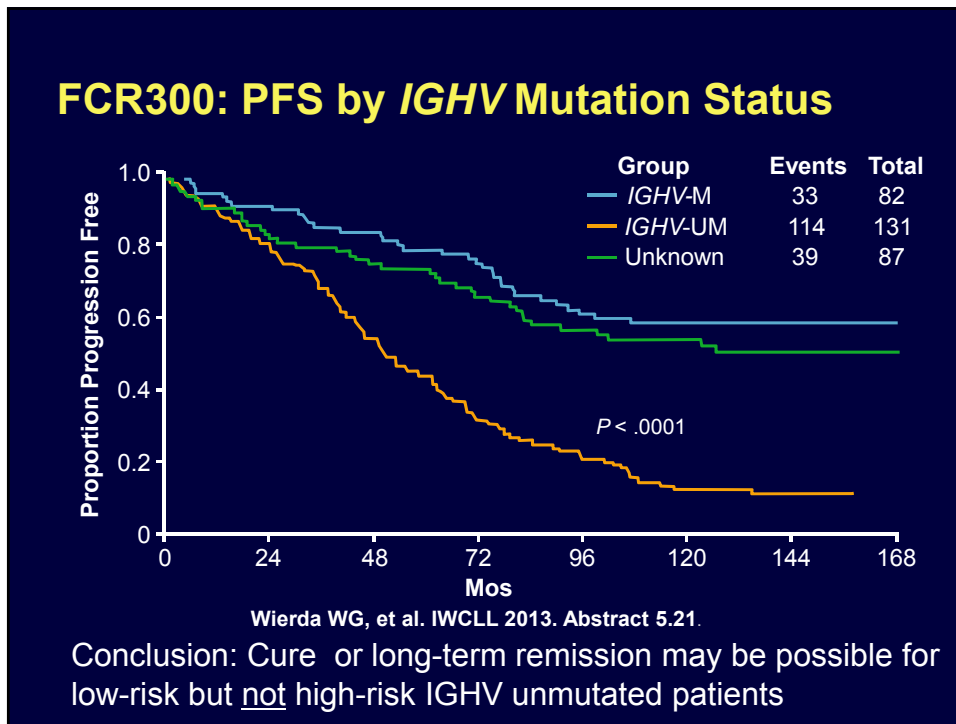
- Long-term follow up FCR data from MDA FCR300 series and German CLL VIII data (not shown) relative to “curability”
- CLL10 data from German CLL Group
- Ibrutinib data with del(17)(p13.1) and approval by FDA for initial use in symptomatic CLL

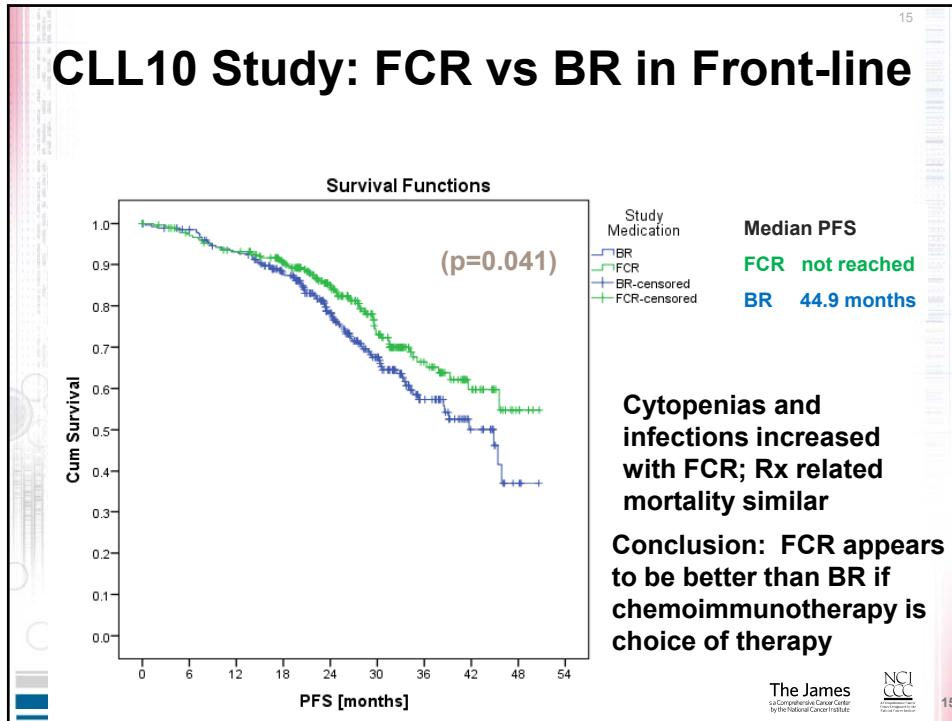
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Ibrutinib: A Potent Irreversible BTK Inhibitor

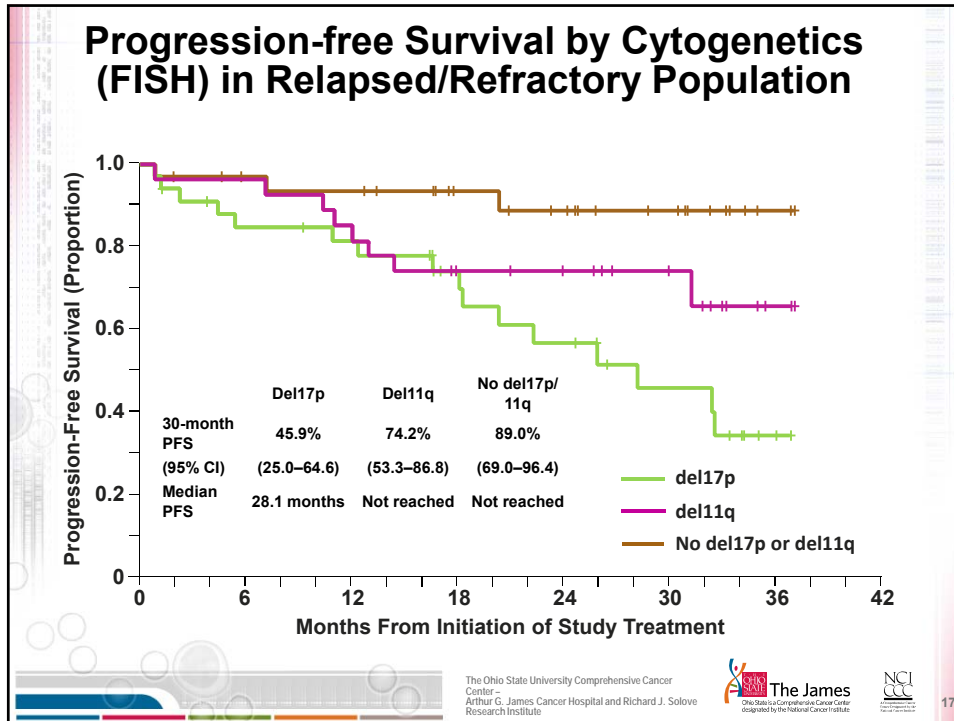
- Forms a specific and irreversible bond with cysteine-481 in BTK
- Potent and irreversible BTK inhibition with $IC_{50} = 0.5 \text{ nM}$
- Blocks BCR signaling; active in canine model of spontaneous lymphoma
- Orally bioavailable
- Once-daily dosing results in 24-hr sustained target inhibition

Honigberg et al: *PNAS* 2010; 107:13075-80

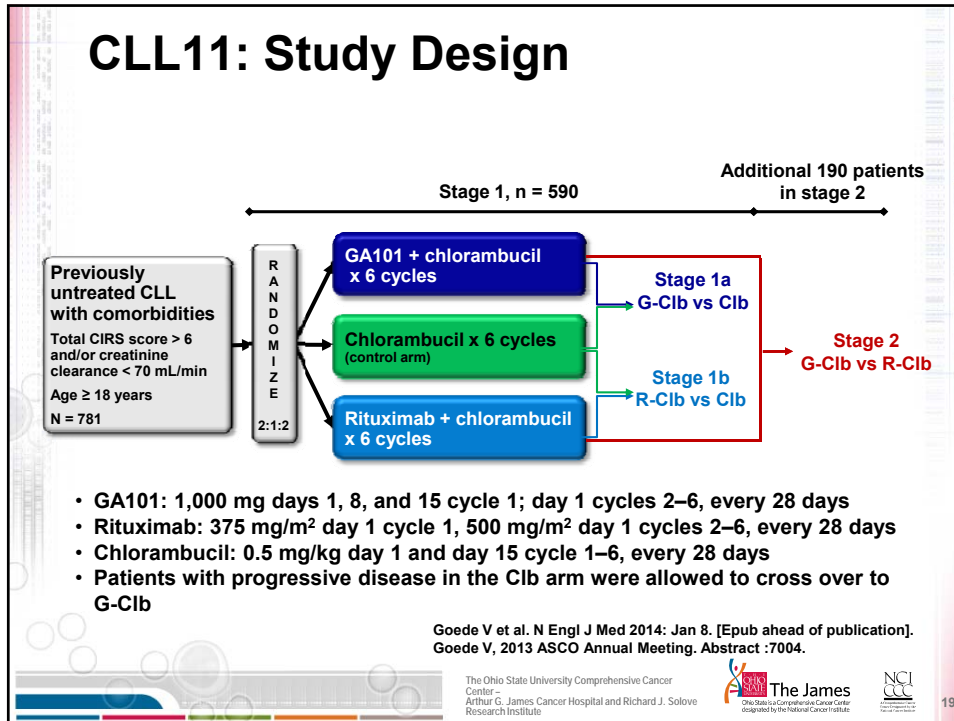
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- ### Approaches to Consider in Elderly Population
- **Not** Fludarabine-based regimens
(Eichhorst Blood 2009, Woyach J Clin Oncol 2012)
 - Bendamustine + rituximab
 - « Slightly higher toxicity rate but feasible in this population
 - Chlorambucil + rituximab
 - « ORR 82% (9% CR, 15% nPR) with median PFS of 23.5 months
 - High-dose methylprednisolone + rituximab
 - « Lower steroid dose typically utilized; favored regimen for del(17p)
 - Obinutuzumab + chlorambucil: A standard of care change
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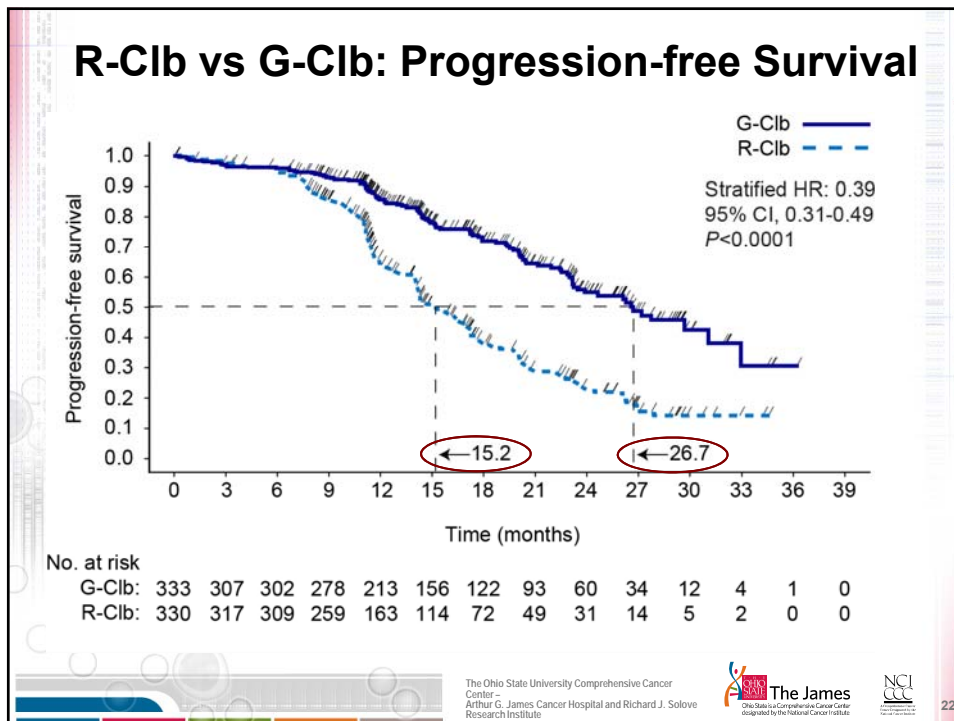
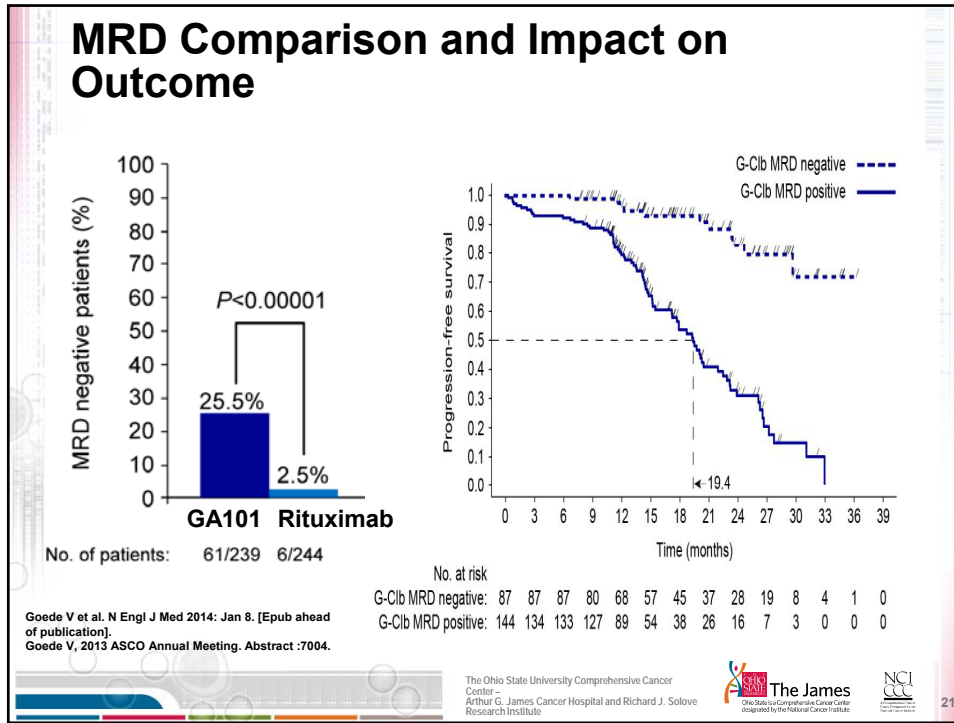


CLL11: Response and Toxicity

- Response
 - CLB 31% ORR, 0% CR
 - CLB + Rituximab 65% ORR, 7% CR
 - CLB + Obinutuzumab 77% ORR, 22% CR
- Toxicity
 - Grade 3 and 4 infusion related events
 - 20% with obinutuzumab versus 4% with rituximab
 - Infusion events with obinutuzumab early (day 1, within minutes of starting infusion sometime)
 - Grade 3 and 4 neutropenia
 - 33% obinutuzumab versus 28% with rituximab
 - No increased risk in serious infections was noted in any arm

p < 0.001 (comparing Rituximab and Obinutuzumab arms for ORR and CR)

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My Approach for Patients > 70

- Repeat interphase cytogenetics, bone marrow
- Clinical trial with strong consideration of non-chemotherapy regimen with 2nd generation BTKi (ACP-196) or A041202 (randomized trial)
- Off trial
 - « Del(17p13.1): Ibrutinib monotherapy
 - « Other genetic features: Obinutuzumab + CLB or bendamustine + rituximab
- Do not use rituximab, alemtuzumab, CLB or rituximab maintenance

Considerations for Relapsed CLL

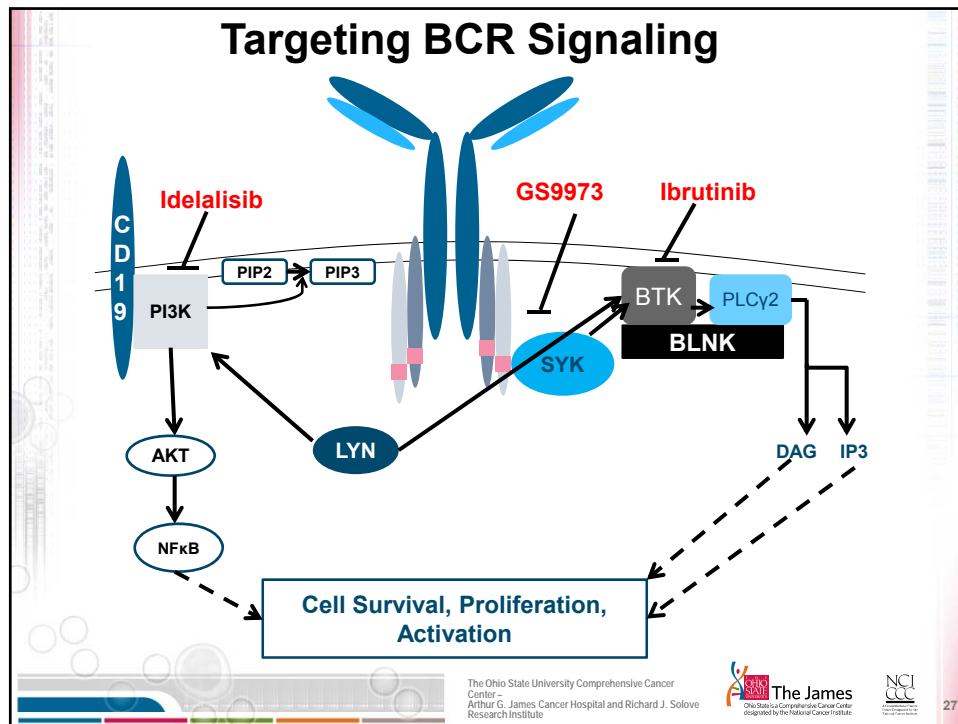
- Outcome of patients at time of relapse depend upon
 - Interphase cytogenetics, β_2M , and stage
 - Prior therapy (i.e. monotherapy or chemoimmunotherapy)
 - Time of remission with last treatment
- Treat relapsed patients when symptomatic only
- Interphase cytogenetics should be repeated prior to initiating salvage therapy
- All patients with cytopenias should have repeat bone marrow to assess for MDS if prior FCR given
- Transplant evaluation (only) should be considered early in this pt population if any unfavorable features present

Past Salvage Regimens for CLL

- Fludarabine, cyclophosphamide, and rituximab (70% ORR, 24% CR, 30.4 m PFS)
- Bendamustine + rituximab (59% ORR, 9% CR, 14 m PFS)
- Lenalidomide + rituximab (66% ORR, 12% CR, 17 m PFS)
- Ofatumumab—50% response, 6m PFS and does not work in bulky del(17p13.1)
- High-dose methylprednisolone + rituximab-30-50% response, ≈12 m PFS but very immunosuppressive
- Alemtuzumab—33% ORR, 2% CR, ≈ 6-12m PFS
- Lymphoma salvage regimens (not effective)

Non-ablative Allogeneic Transplant

- Transplant with traditional ablative regimens carry a 40-50% 100 day mortality in CLL patients age 40-49 making application minimal in past
- Non-ablative approach significantly lowers 1-year mortality (10-20% at year 1)
- Non-ablative approach unique in
 - « Pts with significant adenopathy (> 5 cm) have high relapse rate
 - « Chronic graft-versus-host disease represents big problem in many patients (40-50%) with research now focused toward lowering this
- Role of transplant being redefined in new era or BTKi—still quite debated in young patients

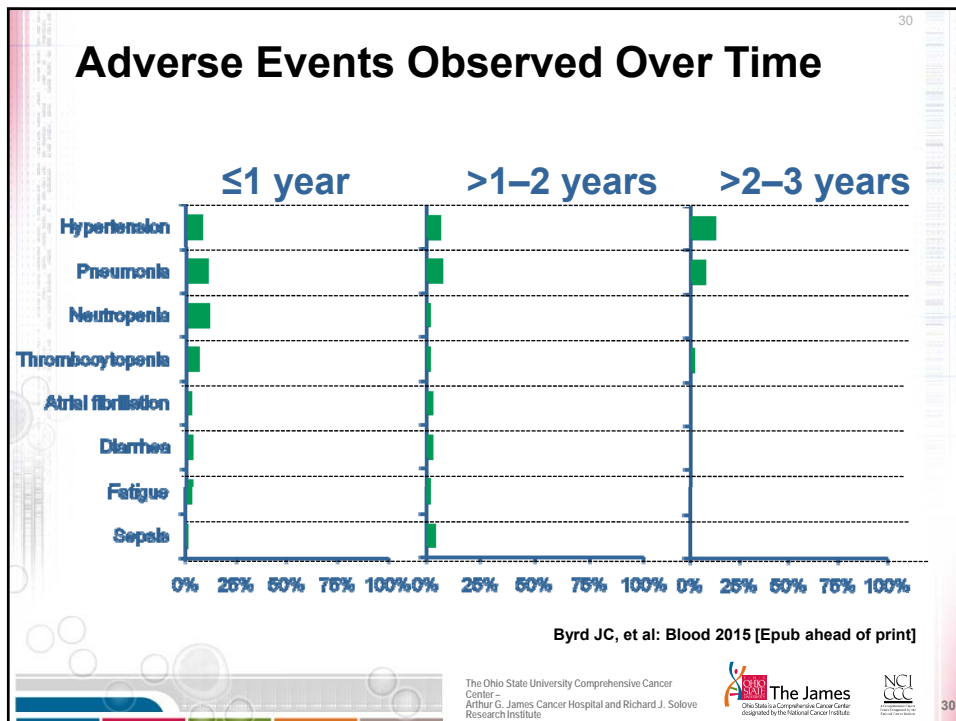
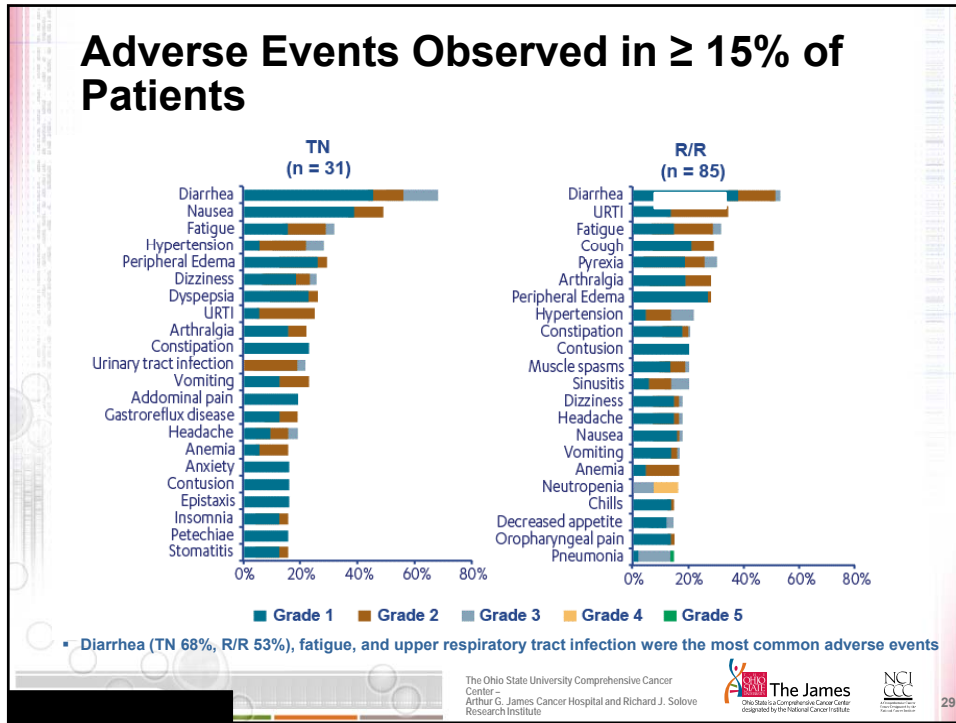


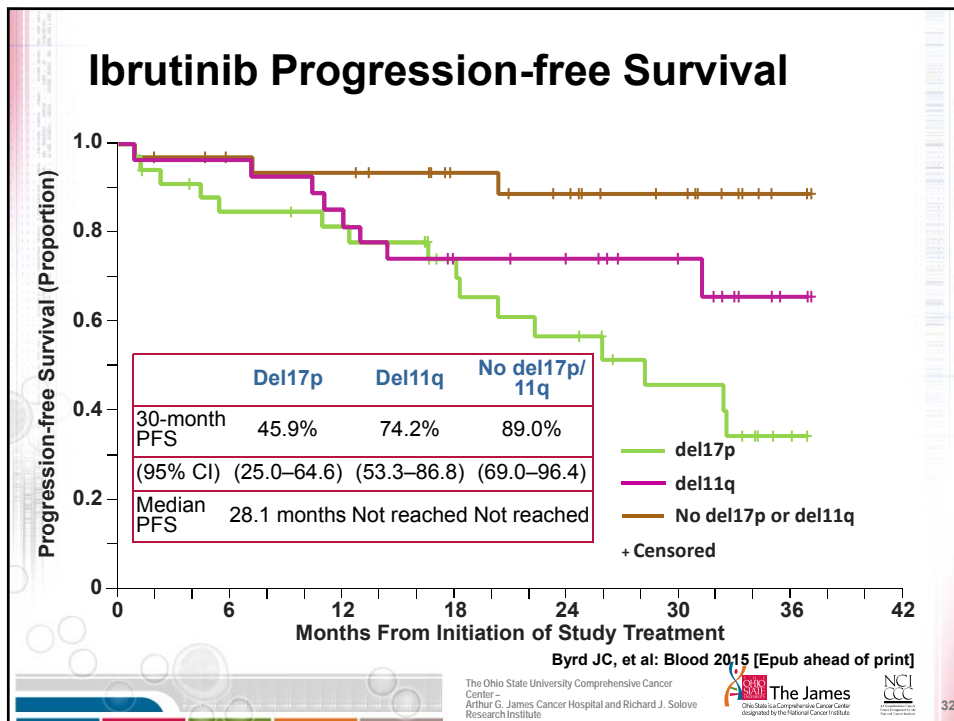
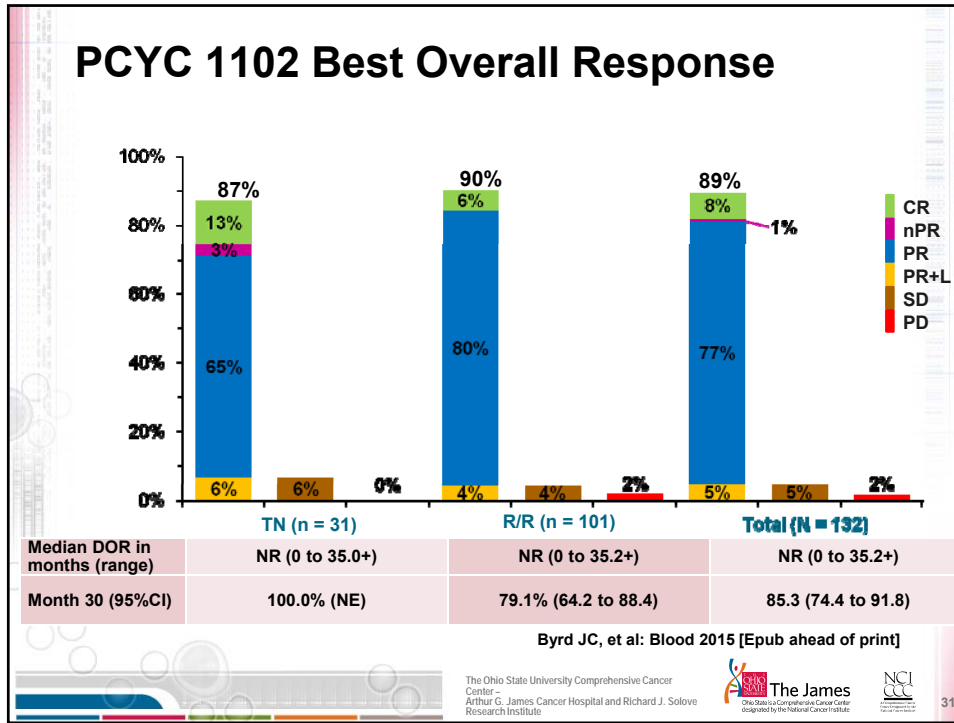
Ibrutinib Pivotal Phase II Study

- 132 patients with CLL enrolled onto this study
 - 31 pts age > 65 years with symptomatic disease but no prior therapy
 - 101 pts of any age with relapsed/refractory disease
 - Median 4 prior therapies
 - 57% Advanced (Stage 3 or 4) disease
 - 35% Del(17)(p13.1)
 - Dosed at 420 mg or 840 mg dose Qd with similar response and PFS (data therefore merged)
 - Early lymphocytosis frequently noted early in therapy but resolves with time

O'Brien S et al: *Lancet Oncol* 15:48-58, 2014
Byrd JC et al: *N Engl J Med* 369:32-2042, 2013
Byrd JC, et al: *Blood* 2015 [Epub ahead of print]

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Phase III Resonate Study in Relapsed/Refractory CLL

- 391 relapsed and refractory pts randomized 1:1 between ibrutinib and ofatumumab
- Outcome dramatically improved with ibrutinib
 - Response (42.1% versus 4%, $p < 0.001$)
 - PFS (median NR versus 8 months; HR 0.22, $p < 0.001$)
 - OS (12 m 90% versus 81%, HR 0.43, $p < 0.005$)
- Toxicity differs between arms
 - Atrial fibrillation (6% versus 1%) > with ibrutinib
 - Grade 1/2 bleeding/ecchymosis (44% versus 12%) > with ibrutinib
 - Rash (8% versus 4%) > with ibrutinib
 - Blurred vision (10% versus 4%) > with ibrutinib
 - Peripheral neuropathy (4 versus 13%) > with ofatumumab
 - Infusion events (0 versus 28%) > with ofatumumab

Byrd JC et al: N Engl J Med 371:213-23, 2014

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Important Management Points About Ibrutinib

- Early lymphocytosis is expected and unless other signs of progression present, therapy should be continued
- Bruising and ecchymosis are noted frequently with ibrutinib but major bleeding uncommon provided
 - Coumadin® (warfarin) therapy is avoided
 - Ibrutinib is held 3-7 days before and after major surgeries
- Management of atrial fibrillation should avoid warfarin and substitute ASA unless at high risk for embolic disease (consider idelalisib)
- Arthralgias, panniculitis, and erythema nodosum associated with this can be managed with short course of steroids
- Benefit of rituximab to ibrutinib unclear at this time

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Future Questions and Application of Ibrutinib in CLL

- Treatment of symptomatic, untreated CLL
- Treatment of early, asymptomatic, but previously untreated CLL with high-risk genomic features
- Combination strategies to increase CR rate, prevent resistance and allow cessation of therapy in a subset of patients
- Identification and treatment of ibrutinib resistant disease

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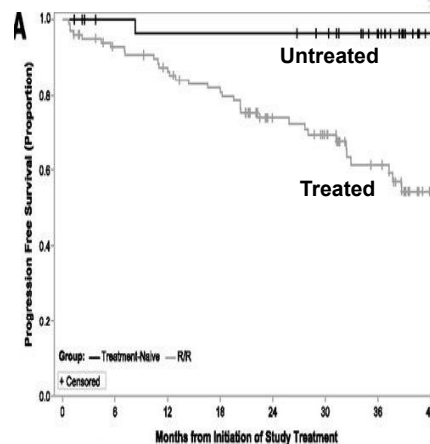
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Ibrutinib in Previously Untreated CLL

- Initial phase 2 study
 - 31 untreated patients > 65 yrs
 - ORR of 84%, with 23% attaining CR, 55% PR, and 6% PR-L.
 - PFS at 30 months—96%

Byrd JC, et al: *Blood* 125:2497-2506, 2015
- Ongoing phase 3 studies
 - CLB versus ibrutinib (age >65 yrs)
 - BR versus IR versus I (age >65 yrs)
 - FCR versus IR (age < 70 yrs)
- Early intervention trials for high-risk, asymptomatic pts ongoing



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Combination Strategies in Ibrutinib

- **Goal: Increase CR rate, PFS, and decrease development of resistance**
 - Ibrutinib + BR (positive study as measured by PFS)
 - Ibrutinib + FCR (DFC)
 - Ibrutinib + CD20 antibody (rituximab, ofatumumab, and obinutuzumab) (MD Anderson, Company)
 - Ibrutinib + Lenalidomide (U Colorado, Stanford, OSU)
 - Ibrutinib + CC-122 (Company)
 - Ibrutinib + Venetoclax (MRC)
 - Ibrutinib + Venetoclax + Obinutuzumab (OSU)
 - Ibrutinib + immune checkpoint inhibitors

Management of Ibrutinib Resistant Disease

- Richter's transformation
 - Occurs most commonly during year 1, withdrawal of ibrutinib can mimic this early due to tumor flare
 - Molecular aberrations uncertain in this patient group
 - Clinical trial or continue ibrutinib with DLBCL regimen
 - Outcome extremely poor, ability of transplant to salvage uncertain
- CLL
 - Occurs virtually always after year 1 of therapy
 - Virtually always associated with C481S BTK or PLCG2 mutation that can be assessed by genotyping blood
 - Therapy with ibrutinib should continue until initiating next therapy to avoid withdrawal tumor flare
 - Response after ibrutinib possible in this group, particularly with alternative targeted therapies (transplant should be considered)

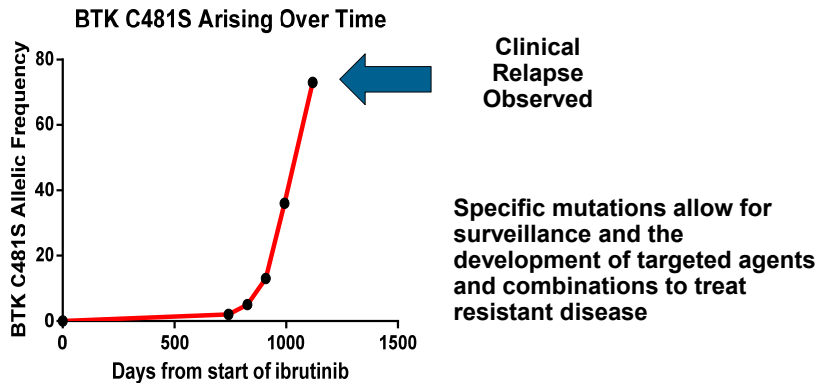
Representative Male Patient on Ibrutinib Developing Resistance



G Lozanski



A Lozanski



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Idelalisib (GS1101, CAL101) in CLL

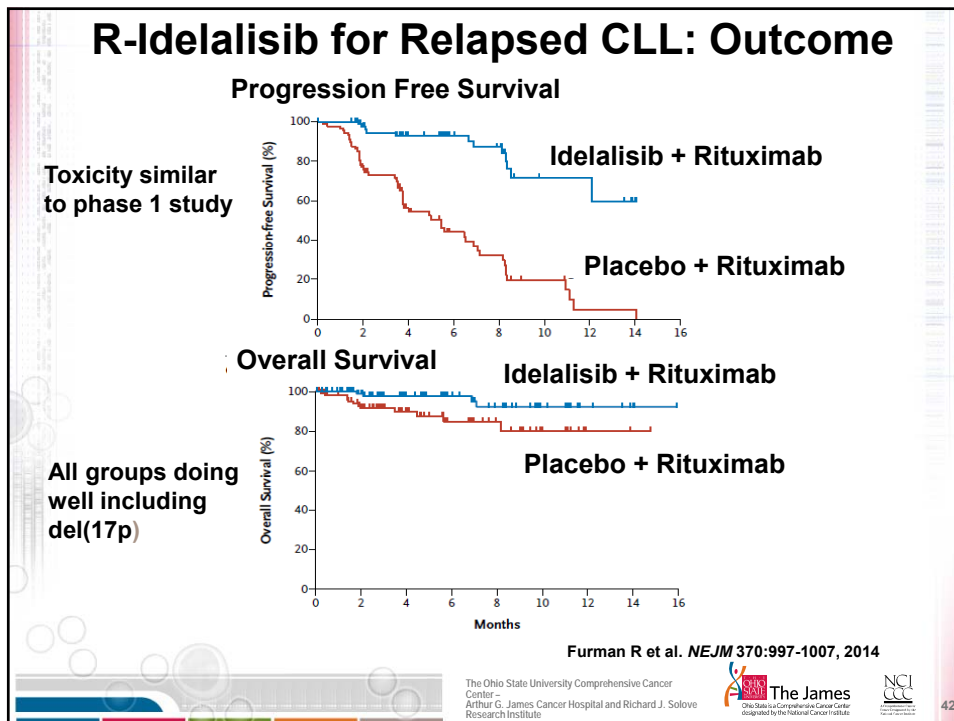
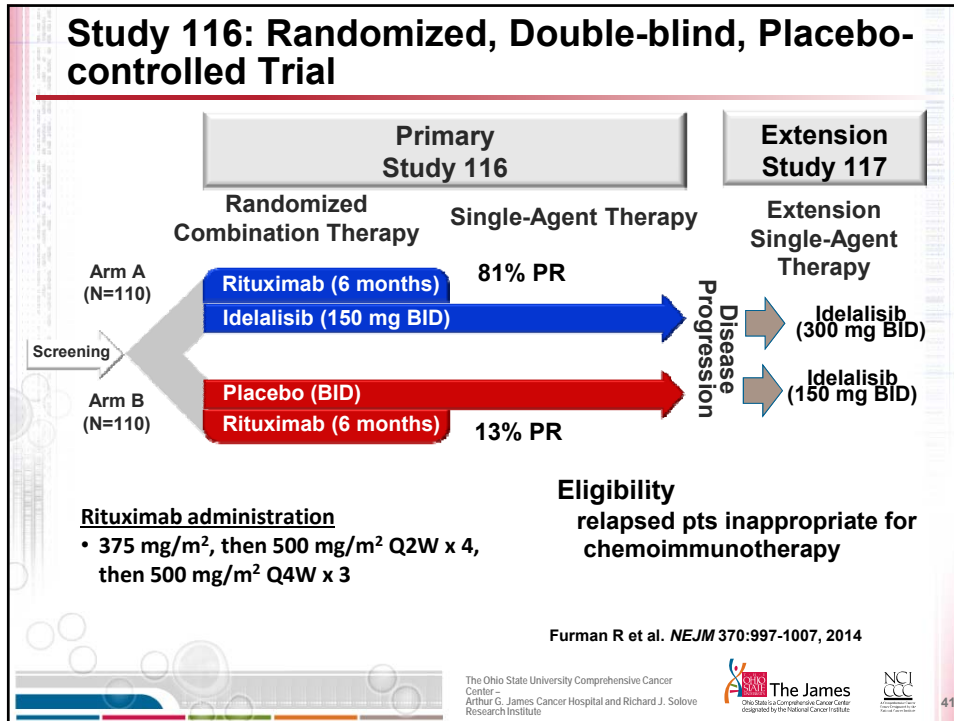
- Idelalisib is an oral agent that targets PI3K-delta providing selectivity thereby allowing good target coverage
- Ph I study in relapsed CLL/NHL with 54 CLL pts
 - Pt demographics median 5 prior Rx, 82%; 31% del(17p13.1)
 - Dose of 150 mg BID based upon Pk and PD
 - Response to therapy remarkable
 - 91% with node/spleen response
 - 24% ORR due to persistent lymphocytosis
 - Median PFS of 18 m; less durable in del(17p)
 - Toxicity modest but includes
 - Early grade 3-4 transaminitis
 - Late hypersensitivity pneumonitis, colitis/diarrhea, and rash

Brown J, et al: *Blood* 123:3390-7 2014

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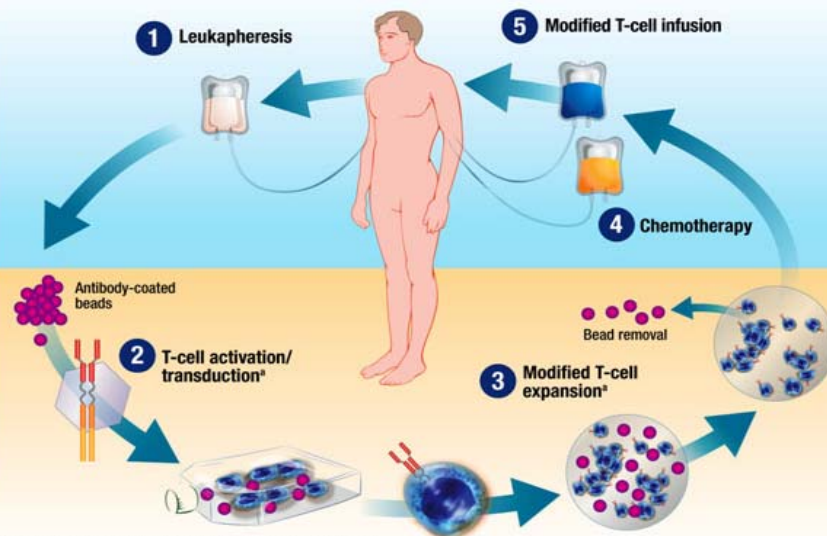
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Where Does Idelalisib Fall in CLL Therapy?

- Idelalisib + rituximab a reasonable therapy for previously treated CLL but many questions remain
 - Where in priority of therapy with ibrutinib
 - Unclear efficacy is similar, particularly in del(17p) pts
 - Need for dual therapy with rituximab raises cost and inconvenience as compared to monotherapy oral agent
 - Toxicity monitoring (LFTs early and colitis late) makes administration more challenging
 - Can be used in the setting of anticoagulation or higher bleeding risk
- My practice is to use idelalisib only when ibrutinib is contraindicated (need for warfarin) or not tolerated
- Ibrutinib works in idelalisib refractory pts; reverse unknown

Chimeric Antigen Receptor T-cell Therapy



Outcome of CAR-T Cells

- Incredibly promising results in refractory pediatric and adult acute lymphoblastic leukemia (80-90% responses)
- Data in CLL somewhat limited
- Some responses in CLL but less than ALL and often only partial
- Major toxicities of CAR-T cells include
 - Cytokine release syndrome
 - Fever and infection
 - Prolonged suppression of normal B-cells (due to CAR-T cells)
 - Need for life-long immunoglobulin production
- Future application of CAR-T cells might include
 - Addition of ibrutinib
 - Use following CLL cytoreduction to lower frequency of cytokine release syndrome

Other Novel Agents in CLL

- **Other small molecule inhibitors**
 - Duvelisib (IPI-145, a p110 δ and p110 γ inhibitor)
 - 2nd generation BTK inhibitor (ACP-196, ONO-4059)
 - Selinexor (XPO1 inhibitor)
 - Venetoclax (bcl-2 but not bcl-xl antagonist)
 - Entospletinib (syk)
 - Many others
- **Antibodies and biologic therapy**
 - TRU-016—CD37 SMIP
 - MOR-208 (CD19 engineered antibody)
 - CD19 Chimeric antigen receptor t-cells
 - CC-122
 - Many others

Important Conclusions

- Select genomic studies can assist in risk stratification of newly diagnosed patients
- CD20-antibody chemoimmunotherapy offers a survival advantage for symptomatic CLL; in no patient should chemotherapy alone be considered
- Patients with del(17p13.1) who require therapy do not respond well to chemoimmunotherapy and should receive ibrutinib
- Kinase inhibitors such as ibrutinib have
 - Altered the recommended time for transplant
 - Have the potential to change treatment paradigm of CLL

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Living Well With CLL

Kimberly Holt, BSN, RN, OCN

June 17, 2015

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OBJECTIVES

Managing Potential Side Effects of Treatment

Aiding Patient/Caregiver In Treatment Adherence

Tips on The Survivorship Challenges of CLL

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Common Side Effects of Newer CLL Therapies

- **IBRUTINIB**- increased risk of bleeding, arthralgias and myalgias, fatigue, hand and foot cramping, bruising, rash, mouth sores, diarrhea, upper respiratory infections and A-fib. **Due to the increased risk for bleeding, Ibrutinib should be held 3 to 7 days prior to procedures, hold time depending on complexity of procedure.**
- **ACP 196**- headaches, infrequent nausea
- **LENALIDOMIDE**- rash
- **ABT-199**- tumor lysis syndrome, low blood counts
- **ZYDELIG**- diarrhea, pneumonitis, colitis
- **IPI-145**- diarrhea
- **KPT**- anorexia and weight loss



"Each capsule contains your medication, plus a treatment for each of its side effects."

****Educate the patient on potential side effects and how they should expect to feel**

****Teach the patient to monitor their temperature and s/sx of infection**

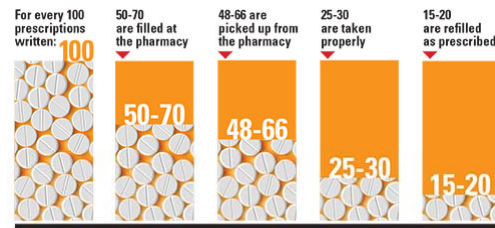
****Upon starting any new therapy, the patient should be instructed to call their physician if they notice any new symptoms that occur while on treatment**

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Aiding Patient/Caregiver In Treatment Adherence



Source: National Association of Chain Drug Stores, Pharmacies: Improving Health, Reducing Costs, July 2010. Based on IMS health data.

(Patient Resource, 2015)

- Consider the cost of medications to the patient; inquire if they are able to afford this; educate patients on MAPs
- The patient should be thoroughly educated on the purpose of each medication in their treatment regimen (including preventives)
- The patient should be taught that even if they 'feel well' to still take their medication regimen as prescribed and to discuss any suggested changes with their physician before altering regimen
- Educate the patient to call their physician's office when running low (2 week supply or less) on specially ordered meds

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Tips on Survivorship Challenges of CLL

Because CLL is a chronic condition, survivors must continually monitor and treat the disease. (Patient Resource, 2015)

- Survivorship is a joint effort between patient, caregiver, and healthcare team
- When seeing a CLL or hematology/oncology specialized physician, patients should be encouraged to maintain a good relationship with their local oncologist and/or PCP as well
- The healthcare team should be easily accessible to the patient (clearly communicate best contact person and numbers, and where applicable, information on email/myChart)
- Encourage the patient to connect with other CLL/cancer survivors (i.e survivorship programs, support groups, blogs, and events such as *LLS Light The Night*[®] and *Pelotonia*[®])

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Tips on Survivorship Challenges of CLL

- Maintain health and wellness
 - Keeping follow-up appointments with your hematologist/oncologist
 - Preventative health screening (PSA, colonoscopy, dermatology, etc)
 - Annual flu vaccination and pneumonia vaccination every five years;
NO LIVE VACCINES

- Aim to avoid contact with persons who have known infections until the infection is resolved. Having CLL puts a patient at greater risk for infection

- Good nutrition, staying active/exercise, and getting plenty of rest

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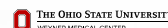
CLL Resources

- **Your Specialized Healthcare Team**
 - Hematologist/oncologist, nurse, social worker, clinical research coordinator

- **Leukemia and Lymphoma Society: www.LLS.org**
 - Blood Cancer Information and Support
 - Copay Assistance Program: (877) 557-2672
 - Telephone/Web Education Programs
 - Education Videos
 - Online Discussion Boards and Chats
 - Consult with an Information Specialist: (800) 955-4572
 - Clinical Trials Information: (800) 955-4572
 - Information for Veterans: (800) 749-8387
 - Other Helpful Organizations: www.LLS.org/resourcedirectory

- **Air Charity Network (Flights to Medical Appts.)**
 - www.airlifthope.org
 - www.lifelinepilots.org
 - www.angelflight.com

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CLL Resources

- **Lodging Assistance**
 - American Cancer Society: 800-227-2345
 - Hope Hollow: www.hopehollow.com
- **Cancer Information and Support**
 - The James Cancer Hospital and Solove Research Institute: <http://cancer.osu.edu>
 - The American Cancer Society: www.cancer.org
 - The National Cancer Institute: www.cancer.gov
 - www.chemocare.com
(Patient friendly chemo education; great instructions on managing side effects)

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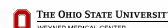
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Medication Assistance Programs

- Imbruvica®: You and I Access Program
www.youandiaccess.com, 1-877-877-3536
 - Assistance with copays if eligibility criteria met and connection with other resources for the uninsured
- Zydelig®: AccessConnect Patient Support Program
www.zydeligaccessconnect.com, 1-844-622-2377
 - Financial support for uninsured and copay assistance for those who meet eligibility criteria
- Patient Access Network Foundation
www.panfoundation.org, 1-866-316-PANF
 - Assistance with medications for patients who have insurance coverage, income must be below 500% of the federal poverty level
- LLS Copay Assistance
www.LLS.org/copay

(Imbruvica, 2015), (Zydelig, 2015), (Patient Access Network Foundation, 2011)

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Questions?




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Thank You

To learn more about Ohio State's cancer program, please visit cancer.osu.edu or follow us in social media:



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CLL: Update on Treatment and Side Effects Management



Question & Answer Session

The speakers' slides are available for download at www.LLS.org/CE

Resources to make informed treatment decisions



Resources from The Leukemia & Lymphoma Society (LLS):

- For more information about blood cancers, other LLS programs, and support for your patients please contact an LLS Information Specialist.

- **TOLL-FREE PHONE:** (800) 955-4572

- **EMAIL:** infocenter@LLS.org

- **Continuing education programs:** www.LLS.org/CE

- **CLL information and resources:** www.LLS.org/leukemia

- Free publications ranging from disease specific information to health insurance options and resources to help patients and families.

- **WEBSITE:** www.LLS.org/publications