Spring/ Summer

# Hematology/ Oncology ACCP PRN Newsletter

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## Greetings from the 2022-2023 Chair

Greetings everyone,

I hope you are all doing well both professionally and personally. As I reflect on the first half of my time as Chair of the ACCP Heme/Onc PRN, I am inspired by the individual and collective efforts of our members within our PRN.

Exciting work is being done through our Membership and Operations, Communications, and Scholarship committees. Our PRN is planning BCOP study groups that will allow members to engage on topics in new ways, as well as a "special edition" virtual rotation for both learners and practicing pharmacists for early Fall. We will be recognizing members through our 2nd year of PRN awards at the 2023 Annual Meeting in November, and continue to support thriving monthly journal clubs and engage in collaborative scholarly work! This newsletter is a great example of collaboration led by the Communications Committee that highlights members and supports the needs of the PRN membership.

The daily impact oncology pharmacists have on patients, teams, and healthcare is immense. We all know how much time, effort, knowledge, and adaptability this requires of us. Being surrounded by members of the PRN who support each other has been a great resource for me, and a privilege. I encourage everyone to continue to reach out to find ways to be involved!

-Erin Zacholski

# Mirvetuximab Soravtansine – A Promising Breakthrough in Platinum Resistant Ovarian Cancer Treatment

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**Introduction**

In November 2022, mirvetuximab soravtansine (MIRV), brand name Elahere, was approved by the Food and Drug Administration (FDA) for adult patients with folate receptor alpha (FRa) positive, platinum-resistant (i.e., failure of treatment with carboplatin) epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have undergone one to three prior systemic treatments.[1] In ovarian cancer, FRa is a marker often associated with poorly differentiated and aggressive tumors and is over expressed in 80% of ovarian cancers.[2] First-line treatment for ovarian cancer is platinum-based chemotherapy, but 15 to 30% of patients with ovarian cancer develop platinum-resistance upon disease progression, making MIRV a novel, targeted therapy that is now available to these patients.[3,4] With ovarian cancer being the fifth most common cancer among women, MIRV holds immense promise in the treatment of platinum resistant ovarian cancer.[5]

**Mechanism of Action**

MIRV consists of a humanized monoclonal antibody (mAb) targeting FRa conjugated to a potent cytotoxic maytansinoid, DM4.[6] MIRV is a first-in-class FRa antibody-drug conjugate (ADC) and it combines the targeted action of an antibody with the cytotoxic effect of a potent chemotherapeutic agent.[7]

The antibody component of MIRV recognizes and binds to FRa receptors expressed on tumor cells. Once the antibody binds to FRa on the cancer cell surface, the ADC is internalized into the cancer cell through receptor-mediated endocytosis. The potent cytotoxic payload maytansinoid, DM4, inhibits cell division by disrupting the function of microtubules, which play a key role in cell replication. Disrupting the microtubules ultimately leads to cell cycle arrest and apoptosis.[8] Thus, MIRV selectively kills cancer cells while reducing toxicity to healthy cells.

**Clinical Trials**

SORAYA Trial

The SORAYA trial was a single-arm, phase III study that included patients (N=106) with platinum-resistant, FRa-positive epithelial ovarian, fallopian tube, or primary peritoneal cancer who had received one to three prior lines of therapy. All patients were required to have received therapy with bevacizumab. Platinum-resistance was defined as disease recurrence within 6 months of treatment with platinum-based chemotherapy. FRα positivity was determined using the Ventana FOLR1 IHC assay.[9]

Patients were given MIRV based on adjusted ideal body weight at a dose of 6 mg/kg as an intravenous infusion every three weeks until unacceptable toxicity or disease progression. Follow-up assessments of tumor response was scheduled every six weeks for the first 36 weeks then every 12 weeks after. The primary outcome was investigator-assessed overall response rate (ORR), and key secondary outcome was median duration of response (mDOR). The ORR was 31.7% and mDOR was 6.9 months. The median overall survival (OS) was 15 months.[10,11] The most common adverse events included blurred vision (41%), keratopathy (36%), and nausea (29%). Adverse events led to discontinuations in 7% of patients.[9]

MIRASOL Trial

The MIRASOL trial was a randomized, phase III trial that compared the use of MIRV versus a single-agent chemotherapy (paclitaxel, liposomal doxorubicin, or topotecan). Like the SORAYA trial, this study included patients (N=453) with platinum-resistant ovarian cancer with high levels of FRα, identified using the Ventana FOLR1 assay, who have been treated with up to three regimens in the past. The primary outcome measure of this trial was progression-free survival (PFS) and secondary outcome measures included ORR and OS.[12]

MIRV was shown to be associated with a 35% reduction in the risk of tumor progression or death in patients who received MIRV versus a single-agent chemotherapy, hazard ratio (HR) 0.65 (95% confidence interval [CI]: 0.52, 0.81; p<0.0001). The median PFS for patients receiving MIRV was 5.62 months compared to 3.98 months for patients who received a single-agent chemotherapy. MIRV also demonstrated significant improvement in OS compared to a single-agent chemotherapy. The median OS was 16.46 months in the MIRV arm compared to 12.75 months in the single-agent chemotherapy arm. With a HR of 0.67 (95% CI: 0.50, 0.89; p=0.0046), there was a 33% reduction in the risk of death with MIRV vs single-agent chemotherapy.

The ORR was 42.3% for the MIRV arm compared to 15.9% in the single-agent chemotherapy arm.[13] The most common adverse events with MIRV included predominantly low-grade ocular adverse events (56%) compared to 9% in the control arm, and gastrointestinal events (70%) compared to 66% in the control arm. Adverse events related to MIRV administration led to discontinuations in 9% of patients, which was lower than the discontinuation rate in the single-agent chemotherapy control arm (16%).[14]

**Adverse Effects**

Common adverse events associated with MIRV are summarized in Table 1 below. It is also recommended to use certain pre-medications (Table 2) to reduce risk infusion reactions and nausea. An eye care plan to reduce risk of ocular toxicity while receiving MIRV is provided in Table 3[8,15].

**Table 1. Adverse Reactions with MIRV in the SORAYA Trial (N=106)**

| Adverse Reaction | All Grades (%) | Grades 3-4 (%) |
|---|---|---|
| **Eye Disorders** | | |
| Vision Impairment | 50 | 7 |
| Keratopathy | 37 | 9 |
| Dry Eye | 27 | 2 |
| Cataract | 18 | 3 |
| Photophobia | 17 | 0 |
| Eye Pain | 10 | 0 |
| **General Disorders** | | |
| Fatigue | 49 | 3 |
| **Gastrointestinal Disorders** | | |
| Nausea | 40 | 0 |
| Abdominal Pain | 36 | 7 |
| Diarrhea | 31 | 3 |
| Constipation | 30 | 1 |
| Vomiting | 19 | 0 |
| **Nervous System Disorders** | | |
| Peripheral Neuropathy | 33 | 2 |

**Table 2. Pre-medications Prior to MIRV Infusion to Prevent Infusion Reactions and Nausea/Vomiting**

| Premedication | Route of Administration | Examples | Administration Time |
|---|---|---|---|
| **Corticosteroid** | Intravenous (IV) | Dexamethasone 10 mg | At least 30 minutes before MIRV infusion |
| **Antihistamine** | Oral or IV | Diphenhydramine 25 to 50 mg | |
| **Antipyretic** | Oral or IV | Acetaminophen 325 to 650 mg | |
| **Antiemetic** | Oral or IV | Ondansetron 8 to 16 mg | Before each dose and as needed for nausea |

**Table 3. Required Eye Care to Prevent Ocular Toxicities**

| | Requirements | Administration Time |
|---|---|---|
| **Ophthalmic Exam** | Conduct an ophthalmic exam including visual acuity and slit lamp exam | Prior to initiation of MIRV, every other cycle for the first 8 cycles, and as clinically indicated |
| **Ophthalmic Topical Steroids** | Prescribe topical corticosteroid eye drops (e.g., dexamethasone 0.1%, prednisolone 1%) upon completion of slit lamp exam | 1 drop of ophthalmic topical steroids in each eye 6 times daily during waking hours starting the day prior to each infusion until day 4; then 1 drop in each eye 4 times daily for days 5-8 of each cycle of MIRV |
| **Lubricating Eye Drops** | Preservative-free lubricating eye drops | Wait at least 10 minutes after ophthalmic topical steroid administration, then instill 1 drop in each eye at least 4 times daily and as needed during treatment with MIRV |

MIRV may lead to severe and/or life-threatening interstitial lung disease (ILD), including pneumonitis. However, it's important to note that these side effects are rare, and the overall benefit vs risk profile of the drug remains favorable.[15]

**Drug Interactions**

Strong CYP3A4 inhibitors (i.e., clarithromycin, erythromycin, diltiazem, itraconazole, ketoconazole, ritonavir, verapamil, and grapefruit) can increase the serum concentration of the cytotoxic payload component, DM4. If strong CYP3A4 inhibitors are administered concomitantly with MIRV, monitor patients for increased toxicities with MIRV.

**Special Populations[15]**

Lactation

Breastfeeding not recommended during treatment with MIRV and for at least 1 month after the last dose.

Hepatic Impairment

Patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN) should avoid use of MIRV. MIRV is not studied in patients with moderate or severe hepatic impairment.

**Patient Education[16]**


Side Effects

Let your doctor know if you experience any worsening visual changes and/or new or worsening respiratory symptoms.

**Conclusion**

MIRV is a breakthrough, targeted, first in class ADC approved for the treatment of platinum-resistant ovarian cancer. Its proven efficacy in early phase and large, randomized clinical trials provide an effective treatment option for patients with FRa positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. The National Comprehensive Cancer Network (NCCN) guidelines list MIRV as a preferred treatment regimen in for patients with FRa positive, platinum-resistant ovarian cancer, who have tried one to three prior treatments.[17] Ocular adverse events were common with MIRV. It is important for the treating oncology team to counsel patients on ocular adverse events and adhering to the eye care plan described in table 2 above to reduce high grade ocular side effects and prevent premature discontinuation of an effective therapy regimen.

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# Nivolumab and Relatlimab Defy Melanoma's Gravity in RELATIVITY-020 Trial

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## Background

Melanoma is usually considered the most serious form of skin cancer. It is one of the most common forms in both men and women, with increased incidence over the course of a patient's life.[1,2] Early diagnosis is crucial for positive survival rates, however, advancements have been made in the treatment of more advanced stages of malignancy. Programmed death 1 (PD-1) and lymphocyte-activation gene 3 (LAG-3) are immune checkpoints known to contribute in cancer to T-cell exhaustion and decrease immune response.[3] Programmed cell death ligand (PD-L1) is related to PD-1 and has also been associated with progression in melanoma.[3]

The RELATIVITY-047 trial published in 2022 examined nivolumab (a PD-1-blocking antibody) and relatlimab (a first-in-class LAG-3-blocking antibody) that showcased improved progression-free survival (PFS) when used in combination (compared to nivolumab alone) for patients with untreated metastatic or unresectable melanoma.[4] The RELATIVITY-020 trial specifically observed patients being treated with this same combination therapy after previously being treated with anti-PD-(L)1-containing regimens.[5]

## Methodology

RELATIVITY-020 was an open-label phase I/IIa trial which had a goal of assessing safety and efficacy of relatlimab and nivolumab in patients with melanoma with progression. The study included patients who must have experienced progression while being treated with one or more anti-PD-L1-containing regimens, or have been on one of these therapies within three months of progression. Objective response rate (ORR) and safety were co-primary endpoints.[5]

The included patients were split into two groups: D1 and D2. Group D1 had more selective criteria requiring only one previous round of only anti-PD-1 (specifically nivolumab or pembrolizumab) containing regimens, though it did allow for patients who had previously undergone therapy with cytotoxic T-lymphocyte associated protein 4 (CTLA-4) inhibitors and v-raf murine sarcoma viral oncogene homolog B (BRAF) inhibitors. D2 allowed multiple cycles of therapy and included anti-PD-1 and anti-PD-L1 therapy. D2 also allowed patients who had received adjuvant or neoadjuvant anti-PD-1 therapy if they progressed within six months of their last adjuvant dose.[5]

### RELATIVITY-020
**(at a glance)**

**D1 ORR** = 12.0% (95% CI, 8.8 to 15.8)
**D2 ORR** = 9.2% (95% CI, 5.2 to 14.7)

**D1 Median PFS** = 2.1 months
**D2 Median PFS** = 3.2 months

**Treatment-related Grade 3 and 4 ADEs:**
D1 = 15.0%
D2 = 12.8%

## Results

The study included 354 patients in the D1 group and 164 in the D2 group. The mean age was 63 and 62 in the D1 and D2 groups respectively, and a majority of each group were white. A majority of the population had previously received immunotherapy, mostly anti-PD-L1 therapy, and many patients previously received chemotherapy (30.2% and 49.4% respectively). The ORR was observed in 351 and 163 of the patients in each group respectively by blinded independent central review (BICR) and was found to be 12% in D1 (95% CI 8.8-15.8) and 9.2% in D2 (95% CI 5.2 to 14.7). Median progression-free survival (PFS) (a secondary outcome) was 2.1 months in D1 (95% CI 1.9 to 3.5) and 3.2 months in D2 (95% CI 1.9-3.6). Patients with a history of therapy with a BRAF or MEK inhibitor treatment had similar objective response rate with those who did not (13.5% with previous therapy, 95% CI 5.6 to 25.8 vs 12.5% without, 95% CI 1.6-38.3). Patients with previous CTLA-4 therapy exposure had an ORR of 11.7% (95% CI 6.8-18.3) compared to 12.1% (95% CI 8.1 to 17.3) in patients without.[5]

For safety outcomes, grade 3 and 4 treatment-related ADEs had an incidence of 15% in D1 and 12.8% in D2 with no treatment-related deaths. There was one occurrence of grade 3 myocarditis. In general, treatment related adverse events (TRAEs) occurred in 67.5% of D1 patients and 68.9% of D2 patients, and these TRAEs led to discontinuation in 5.1% and 4.3% of patients in each group respectively. The most common TRAEs in D1 were rash (7.3%), hypothyroidism/thyroiditis

## Discussion

The RELATIVITY-020 trial showcased benefit in patients expressing PD-L1 and LAG-3, but also showcased benefit in patients without that expression, suggesting that while these treatments may be effective, their targets also might not be the sole markers to seek for choosing a treatment regimen. Limitations to this study include its open-label single-arm study design, the limited diversity of its patient population, and its limited duration. Strengths include its inclusion of patients with many different historical treatment modalities and an examination of the sub-group in the D groups which represents a specific group of patients who struggle to find appropriate treatment in practice.[5]

## Conclusion

The RELATIVITY-020 trial has demonstrated efficacy of nivolumab/relatlimab in patients with previous therapy on PD-1 and PD-L1 regimens, while the RELATIVITY-047 trial showcased efficacy and safety in patients previously not treated for advanced melanoma.[4,5] The FDA granted approval for the combination product, Opdualag (nivolumab and relatlimab-rmbw) in 2022 based on the results of RELATIVITY-047 with an indication for use in adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.[4-7] While this indication did not exclude patients with heavy pre-treatment history, RELATIVITY-020 showed that this combination therapy is a viable and safe option, even in patients who have previously attempted therapy with similar treatment modalities and molecular targets.

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# ECOG1910: A game changer for the treatment of adult patients with MRD negative B-cell acute lymphoblastic leukemia

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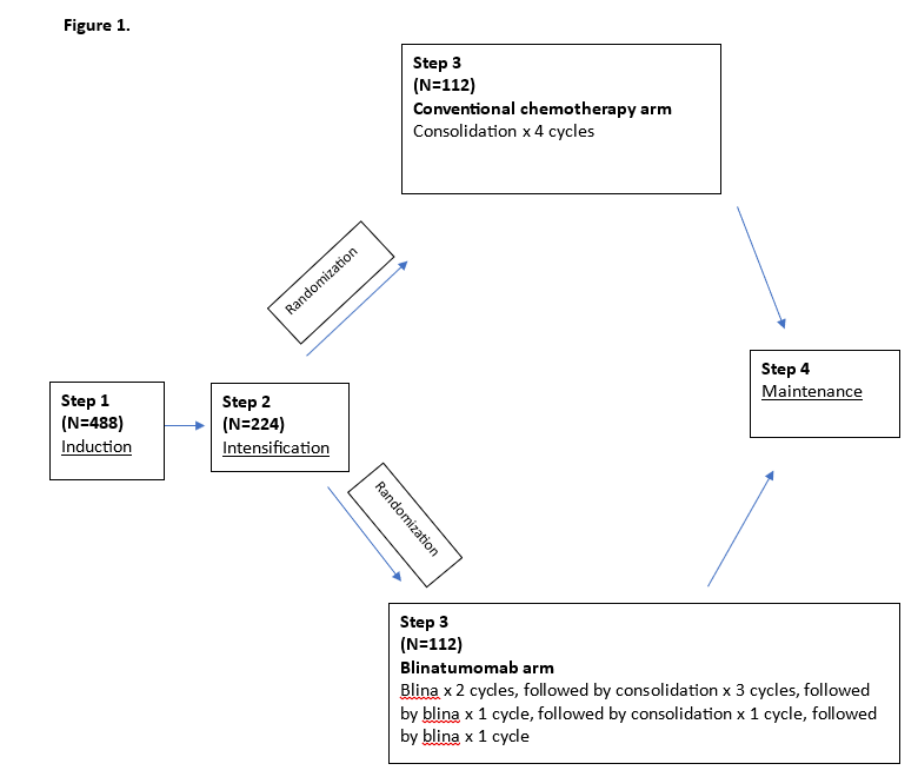
**Background**

Although significant advances have been made in the prognosis and treatment of acute lymphoblastic leukemia (ALL), the bulk of these improvements have been confined to the pediatric arena. While 5-year survival for standard risk B-ALL in pediatric patients has risen from ~ 30% in the early 1970's to > 90% today, survival gains in adult ALL have been much less robust.[1,2] The reasons for this lag are multi-faceted but include higher relapse rates for adult patients due to more mutated baseline disease and their inability to handle the intensive chemotherapy regimens commonly utilized in children. In recent years, therapeutic approaches for improving adult ALL survival have generally focused on three core strategies. First, the incorporation of more pediatric-inspired regimens for the treatment of younger adult and fit older patients. Second, the assessment of measurable residual disease (MRD) as an early signal for treatment intensification in MRD positive (+) patients. Third, the evaluation of novel targeted therapies for ALL, such as blinatumomab, in the frontline setting.

Blinatumomab is a bispecific T-cell engager molecule (BiTE) that combines antibody fragments targeted against both CD19 and CD3. By enhancing the proximity and interaction of cytotoxic T-cells with CD19+ lymphoblasts, blinatumomab promotes immune-mediated elimination and optimizes T-cell lysis. Due to its' short half-life, a treatment cycle is administered as a continuous infusion over 4 weeks. Following initial approval in 2014 for the treatment of adults with relapsed/refractory B-cell ALL, its' use in relapsed ALL has expanded to the Philadelphia chromosome positive (Ph+) and pediatric setting. In 2018, blinatumomab gained FDA approval for the treatment of adult B-cell ALL patients in complete remission (CR) who remained MRD positive despite completion of intensive chemotherapy. This approval was based on a phase 2 trial in adults with first/late complete remission who remained MRD (+) after at least 3 cycles of chemotherapy. 88% of patients were able to achieve an MRD response and 18-month relapse free survival (RFS) and overall survival (OS) were 53% and 67% respectively.[3] The positive results from this study, in conjunction with notable early findings from ongoing clinical evaluations, have spurred further exploration of the potential benefit of blinatumomab in patients with MRD (-) disease.

**Methods**

The ECOG-ACRIN E1910 trial was a phase III randomized study that sought to evaluate whether the addition of blinatumomab consolidation could improve OS in newly diagnosed, MRD (-), B-cell ALL patients as compared to conventional chemotherapy (CC) alone. Patients between the ages of 30 and 70 with Ph (-) ALL were eligible for enrollment. All patients received a BFM-like extended induction regimen adapted from the E2993/UKALLXII trial. This regimen is notable for the prolongation of its induction cycle, the incorporation of pegaspargase for patients under the age of 55, and the addition of Rituximab for CD20+ patients. If patients were in morphologic complete remission with or without complete count recovery (CR/CRi) following their induction cycle, they then went on to receive an intensification cycle of chemotherapy, followed by a bone marrow assessment of remission and an assessment of MRD via flow cytometry. MRD negativity was defined as < 0.01%. If patients were in remission and MRD (-), they were then randomized to receive either CC alone or CC in conjunction with 4 cycles of blinatumomab. All randomized patients in the study received the same number of cycles and doses of chemotherapy. Patients who completed consolidation chemotherapy with or without blinatumomab, then went on to receive 2.5 years of POMP maintenance therapy timed from the start of that patient's first induction cycle. A more detailed diagram of the study design and timing of blinatumomab administration can be seen in **Figure 1**. Patients were allowed to proceed to allogeneic hematopoietic cell transplant (HCT) at the discretion of the treating physician but were encouraged to delay assessment until at least two full cycles of blinatumomab had been given. Of note, following the approval of blinatumomab for MRD positive disease in 2018, the study was amended such that all patients who were MRD positive after intensification were assigned to the blinatumomab arm of the trial and were no longer randomized.




## Results

In patients able to achieve MRD negativity following induction and intensification chemotherapy, blinatumomab + CC demonstrated significant improvement in overall survival as compared to CC alone. Of the 488 patients initially enrolled, 224 patients were able to achieve MRD negativity and proceed to randomization. Median OS has yet to be reached in the blinatumomab arm vs 71.4 months in the CC arm (hazard ratio of 0.42, 95% CI: 0.24-0.75; p value = 0.003). At the third interim analysis, 17 patients had died in the blinatumomab arm vs 39 patients in the CC arm with the upper boundary for efficacy analysis crossed in favor of the blinatumomab group. No significant safety concerns have been noted by the authors thus far.

## Discussion

The addition of blinatumomab to conventional consolidation chemotherapy in MRD (-) adult patients with newly diagnosed B-cell ALL demonstrated a significant survival advantage vs CC alone. This headline result has sweeping implications for the field of leukemia and is likely to usher in a new standard of care for the treatment of adult B-cell ALL. However, this outcome now leads to several questions regarding the use of blinatumomab moving forward. First, what role should blinatumomab currently play in the upfront treating setting for newly diagnosed B-cell ALL? In the phase 3 TOWER trial assessing adult patients with relapsed/refractory B-ALL, blinatumomab demonstrated better survival and improved remission rates vs standard of care chemotherapy. However, a pre-specified subgroup analysis found that over 65% of patients with < 50% BM blasts at drug initiation were able to achieve CR/CRh as compared to only 34% of patients with > 50% BM blasts.[7] This accords with results from other clinical trials demonstrating not only improved response rates but less toxicity with blinatumomab for patients with lower baseline disease prior to treatment.[5,8] Studies evaluating what baseline disease threshold should be targeted prior to blinatumomab initiation will be critical for ensuring improved efficacy without the potential cost of excess blinatumomab toxicity. A notable secondary endpoint from this study, yet to be analyzed, is a survival comparison for patients who were MRD (+) upon randomization and then converted to MRD negativity after two cycles of blinatumomab vs patients who remained MRD (-) throughout the initial induction and randomization evaluations. Similar treatment outcomes between these two groups could potentially lead to earlier incorporation of blinatumomab for patients who are persistently MRD (+) and identify potential candidates for blinatumomab consolidation monotherapy, a promising therapeutic strategy for older/elderly patients who cannot typically handle numerous cycles of consolidation chemotherapy. Indeed, in a post-hoc analysis of patients from the phase 2 BLAST trial, 6 of the 36 patients who achieved a complete MRD response following blinatumomab and did not go on to receive HSCT, were able to achieve 5-year remission status in the absence of additional CC.[9] In summary, the early results from this trial are extremely exciting for the field of adult B-cell ALL and should hopefully serve as a springboard for further investigations of the optimal place in the ALL landscape moving forward.

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# Cardio-oncology Overview: Implementing Primary Prevention Strategies with Oral Targeted Therapies

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Cardiovascular disease is the primary driver of morbidity and mortality in the United States, with cancer following shortly behind. The risk factors for these two comorbidities closely align, thus providing an opportunity for therapy optimization and potentially prolonging the lives of patients. Cardio-oncology is an area of practice comprising two primary facets: cardio-toxicity associated with oncology treatment and risk related to survivorship following cancer cure [1]. Upon cancer diagnosis, it is recommended to assess the cardio-toxic potential of treatment and to consider initiation of preventive measures per the 2022 Cardio-Oncology Guidelines provided by the European Society of Cardiology (ESC) and the International Cardio-Oncology Society (IC-OS) [2]. There is a wide variety of oncolytic-related cardiotoxicity presentations including hypertension, venous thrombo-embolism (VTE), coronary artery disease (CAD), heart failure, valvular disease, and arrhythmias. With increased overall survival and improved prognosis of cancer patients, there has been an up-tick in patients warranting a CV risk assessment and implementation of preventative measures upon cancer treatment initiation [3].

Parenteral anthracyclines and anti-HER2 therapies are well known for their potential to decrease the ejection fraction; however, cardio-oncology management extends far past these agents. In this cardio-oncology update, we will highlight two targeted oral therapies with recommended primary prevention measures.

**Ribociclib and QTc Prolongation**

Cyclin-dependent kinase 4 and 6 inhibitors (CDK4/6i) are generally indicated for the use of patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant [5]. Of the three currently approved CDK4/6i (abemaciclib, ribociclib, and palbociclib), ribociclib is generally favored in clinical practice given it has demonstrated an overall survival benefit for this patient population in the MONALEESA 7 trial, where abemaciclib and palbociclib have only demonstrated progression-free survival benefits in this population to date [5,6]. Furthermore, as of ASCO 2023, NATALEE demonstrated a potential role for ribociclib in early stage HR positive and HER2 negative breast cancer, thus allowing for more CDK4/6i use earlier on in patient's therapy [7].

However, when comparing the safety profiles of the three CDK4/6i, it is worth noting that ribociclib is associated with QTc prolongation more often than its counterparts. It is believed that this occurs in a dose-dependent manner, generally within the initial 4 weeks of therapy [8]. This adverse event is believed to occur due to ribociclib's modification of gene expression on the myocytes. It is suspected that ribociclib leads to a down-regulation of *KCNH2* expression and an up-regulation of *SCN5A* and *SNTA1* that both impact the *Ikr* current and voltage-gated sodium channels. Ultimately, this causes a prolongation in the QTc that puts the patient at an increased risk of arrhythmias [9]. In the original MONALEESA trials, 6% of patients had an increase of >60 milliseconds in their ECG from baseline, though there were no cases of torsades de pointes [6,10,11].

When considering the clinical implications of this QTc prolongation risk, recommendations primarily surround monitoring of ECGs at select timepoints. Strict guidance is provided in the prescribing information on the scheduling of ribociclib initiation, drug-drug interactions, ECG monitoring, and electrolyte monitoring [5]. Furthermore, guidance is provided regarding dose modifications and the need to hold therapy with different grades of QTc prolongation. Notably, the prescribing information specifies the QTc formula of choice for ribociclib is QTcF or the Fridericia formula. This is due to the MONALEESA trials measuring the QTc using the QTcF, but also due to the risks associated with using the more commonly used Bazett formula. Table 1 describes considerations that could drive one to select one formula versus another. The QTcF is the formula of choice per the IC-OS.

**Table 1. Primary QTc Formula**

| QTcB (Bazett) | QTcF (Fridericia) | QTcFa (Framingham) |
|---|---|---|
| $QT/RR^{1/2}$ | $QT/RR^{1/3}$ | QT + 0.154(1-RR) |
| Thought to overestimate during tachycardia and underestimate in bradycardia | Considered to be more accurate during tachycardia | More uniform correction over a wider range of heart rates and rhythms |
| Most commonly used | Included in MONALEESA trials | |

RR=60/heart rate

It is worth considering the clinical implications that correcting QT using the QTcB could have in comparison to using QTcF. There have been a couple studies to date describing this, including one published by *Al-Tweigeri, et al.* in 2021 [12]. This was a case report of 82 patients in which baseline ECG used the QTcB formula prior to ribociclib initiation. 23% of these patients were excluded from initiation due to the baseline QTc being > 450ms per the prescribing information guidance. However, when re-calculating these ECGs using the QTcF formula, 17 of the 19 excluded patients were eligible for initiation of therapy. The median QTcB formula in this study was 471 ms versus 439 ms for the QTcF. This highlights the importance of using the appropriate formula for initiation. Additionally, a recent publication in JAMA Oncology described the importance of the correct formula usage when initiating oral chemotherapy [13]. This study included a total of 6881 patients and demonstrated by using the Bazett formula, the median QTc value 26.4 ms higher than the median QTcF. This study also highlighted that the use of QTcB resulted in a 3-fold increase in CTCAE grade 3 QTc prolongation when compared to other formulas, and was likely associated with inappropriate changes in clinical management due to potential over-estimation of the QTc. These inappropriate clinical changes included making changes not in accordance with the FDA labeling and modifying therapy with a prolonged QTcB, but not with a QTcF. In summary, pharmacists should be aware that using the appropriate formula is imperative for accurate ECG interpretation when initiating a patient on any QTc prolonging oncolytic, especially ribociclib. Furthermore, it is important that pharmacists recognize what their institution has adopted to be their standard QTc formula, given that this can vary between different centers and impact ECG interpretation.

**BCR-ABL Tyrosine Kinase Inhibitors (TKIs)**

BCR-ABL TKIs are a class of medications commonly used for chronic myeloid leukemia (CML). These medications have completely altered the CML landscape following the identification of the BCR-ABL mutation, making CML a lifetime diagnosis and very rarely warranting patients to need a hematopoietic stem cell transplant. The BCR-ABL TKI class is made up of four generations, with each generation being associated with individual CV risks [14]. Table 2 lists the different TKIs and their associated CV toxicities, with the most notable CV-toxic agent being ponatinib.

There has been an effort to standardize the CV assessment for patients upon initiation of oral TKIs due to these associated risks. Barber *et al.* published a review in 2017 describing a method coined the 'ABCDE' steps (Figure 1). This study proposed that if patients were initiated on nilotinib or ponatinib, the TKIs that run the highest risk for cardiovascular adverse events, that providers employ this monitoring tool at baseline and every 3-6 months throughout therapy to ensure no modifications to therapy are warranted. Through close monitoring of patients as proposed in this review, therapy can be optimized on two fronts: cardiology and oncology.

**Table 2. BCR-ABL TKI Overview and Potential CV Toxicity**

| Generation | Medication | Potential CV Toxicity |
|---|---|---|
| First | Imatinib | Heart failure (low clinical significance) |
| Second | Nilotinib | Nilotinib: QTc prolongation, hyperglycemia, hypertension, hyperlipidemia, vascular events |
| | Bosutinib | |
| | Dasatinib | Dasatinib: pulmonary hypertension, vascular events, pleural/pericardial effusions |
| Third | Ponatinib | Vascular events (arterial occlusive events) and hypertension |
| Fourth | Asciminib | Hypertension, heart failure (low clinical significance), vascular events (low clinical significance) |

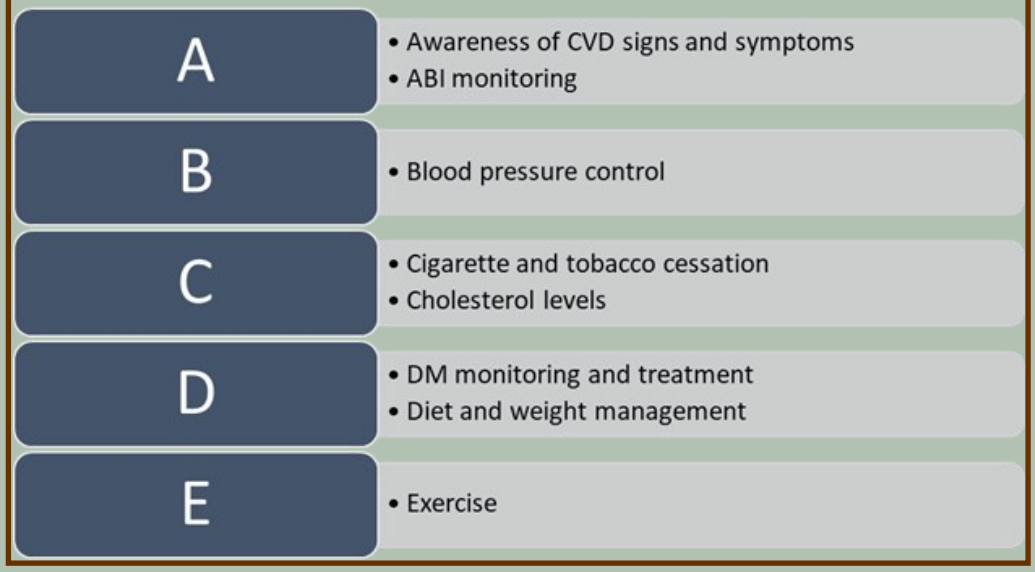
**Ponatinib and Primary Prevention Strategies**

Ponatinib is the BCR-ABL TKI most notoriously associated with CV toxicity. Ponatinib is used in a specific CML-niche when a patient has developed resistance through a T315I mutation. This mutation precludes the patients from previous generation TKIs; however, ponatinib is able to overcome this resistance mechanism. For this reason, ponatinib received accelerated approval by the FDA in 2012. However, it was subsequently removed from the market about one year after due to the 31% risk of arterial occlusive events (AOEs) demonstrated in the PACE trial [16]. Approximately one year following market removal, ponatinib's use was reinstated with an added a black-box warning for AOEs and a recommendation to be used concomitantly with aspirin 81 mg daily [17].

Since this recommendation, there have been several studies assessing the optimization of ponatinib therapy. Because toxicity profile for BCR-ABL TKIs is thought to be dose-dependent, the OPTIC trial explored decreasing ponatinib dose to 15 mg daily from an initial 45 mg daily following dose response. With the results of the OPTIC trial, clinicians have observed better response rates and safety profiles following dose reduction. Aspirin prophylaxis with ponatinib has become the standard of care; however, given that doses are now reduced following therapy response, clinicians now question the necessity of aspirin prophylaxis for those receiving ponatinib [14]. Benefit has been demonstrated in patients over 60 years of age or with increased CV risk scores, thus suggesting that aspirin prophylaxis should remain standard of care until future research has been published truly demonstrating the benefit and risk.

The estimated incidence of ponatinib-induced hypertension is as high as 68%. The mechanism by which ponatinib increases patients' risks of AOEs and hypertension is due to the added activity that this medication has on VEG-F [14,18]. Because of the suspected mechanism, it is recommended to manage ponatinib-induced hypertension similarly to VEG-F inhibitor induced hypertension. The general recommended treatment includes ACE inhibition (ACEi) and the use of angiotensin-receptor blockers (ARB) [2,18]. The use of amlodipine, thiazide diuretics, and carvedilol have also been studied with demonstrated success; however, there is more data supporting the use of ACEis or ARBs, thus potentially favoring these agents. Blood pressure should be monitored closely in these patients, with the goal blood pressure <140/90 mmHg, unless the patient has other comorbidities that warrant lower goals (e.g. diabetes mellitus, chronic kidney disease, or CVD).

**Figure 1. ABCDE Steps to Prevent CVD in Patients with CML on a BCR-ABL TKI**




CVD - cardio-vascular disease; ABI - ankle brachial index; DM - diabetes mellitus

**Conclusion**

Cardio-oncology is a vast subspecialty encompassing considerations for CV toxicity that span beyond those previously known with parenteral agents. Pharmacists can play a key role in ensuring appropriate cardiovascular monitoring is completed prior to initiation and throughout therapy. Additionally, pharmacists can advocate for the addition of concomitant prophylactic strategies in hopes to mitigate toxicities (e.g. aspirin, blood pressure agents, statins). It is imperative for those receiving oral agents in the community to be adequately educated about the signs and symptoms of toxicities in which to seek care. With time, it will be exciting to see where this subspecialty guides us and how cardiovascular considerations will impact cancer care.

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# Bispecific Antibodies: The Future is Bright for BiTEs

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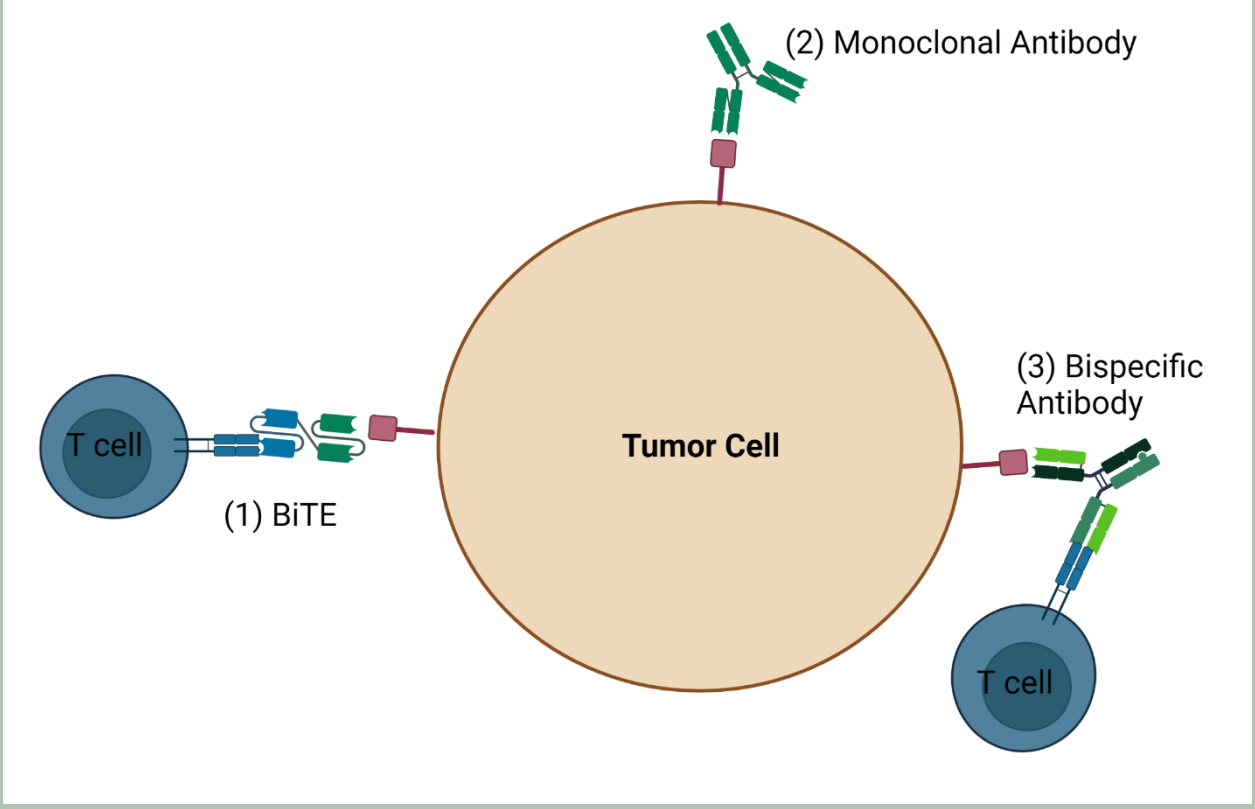
Bi-specific antibodies have become a prominent new direction of therapy for oncology, with teclistamab approved in 2022 as the first bi-specific antibody for multiple myeloma, and more recently epcoritamab in May 2023 for diffuse large B-cell lymphoma. These novel drugs have a unique mechanism of action that drives their efficacy in oncology disease states, which will be the focus of this piece.

The development of bi-specific antibodies was one built upon the success of monoclonal antibodies such as rituximab for lymphoma, leading to the development of drugs that could target different pathways or cells. Bi- or even poly-specific antibodies have demonstrated several advantages over monospecific antibodies, such as a higher engagement of T-cells or NK cells, stability, and more efficient binding to the target[1]. This efficacy does come at the cost of a higher risk of immunogenicity or cytokine release syndrome[1]. Catumaxomab, a rat-mouse hybrid bi-specific antibody targeting CD3 and EpCAM, was the first bi-specific approved in the US but was withdrawn from the market due to poor commercial success. Blinatumomab, a BiTE targeting CD3 and CD19 for acute B-cell lymphoblastic leukemia (B-ALL), is the first bi-specific approved in the US that is still currently on the market[2].

It is common to see these drugs be referred to in clinical practice as "BiTE" therapies. However, it is important to distinguish that not all bi-specific antibodies are BiTE therapies—BiTE is actually a trademarked term by Amgen Inc, an acronym for "Bi-specific T-cell engagers"[3]. Though BiTE seems to be becoming a genericized trademark like 'Thermos' and 'Styrofoam', it is important to note the distinction.

Bi-specific antibodies are named thus because they consist of antibodies targeting two different receptors. Most commonly, the bi-specific antibodies in oncology will target CD3 on T-cells and an antigen specific to the cancer cell, such as EpCAM or BCMA. This is achieved through one of several methods or formats of antibody design. The first is fragment-based (used in BiTE) in which fragments of antibodies are combined without an Fc region; these have the advantage of being relatively simple to manufacture with high yields but have stability and half-life issues since they do not have the Fc region of a 'normal' antibody[4]. The other two forms, symmetric and asymmetric, are designed with the Fc region typical of a normal human antibody through the fusion of antibody fragments to regular antibody molecules[4]. Simplified visualizations of these formats are included below.


These therapies achieve their heightened efficacy through the dual action of binding to CD3 receptors on T-cells and binding to the antigens expressed on the surface of cancer cells—effectively activating the immune system and bringing it to its target. This explains some drugs such as teclistamab being referred to as 'CD3-redirecting therapies', in that they are redirecting CD3+ T-cells (in the case of teclistamab, redirected to BCMA+ myeloma cells)[5]. The activation of the immune system through CD3 also explains the term "T-cell engagers" in BiTE, since blinatumomab 'engages' CD3+ T-cells to bind to CD19+ B-cells in leukemia.[6]




This figure shows a simplified comparison between BiTE, bispecific antibodies, and monoclonal antibodies in regard to their interactions with tumor cells and their mechanism of action in oncology. As shown, the BiTE and bispecific antibodies bind to receptors on both T-cells and the surface of tumor cells, engaging T-cells and redirecting them to the targeted cancer cell. In contrast, the monoclonal antibody binds to only one target, the tumor cell surface antigen.

The development of bi-specific antibodies is a rapidly developing field, with drugs being developed for a wide range of cancers with targets such as MET in lung cancer[7], STAT3 and KRAS[8], and many others. The potential utility of these drugs across hematology and oncology disease states make this a drug class to watch.

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# KMT2A In Leukemia

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The KMT2A gene, also known as lysine methyltransferase 2A or MLL, is part of the KMT2 family, and broadly functions as an epigenetic modifier.[1,2] This family of genes encodes for histone methyltransferase enzymes, one of many histone-modifying enzymes, to aide in regulating gene transcription. Once connected to a co-activator it regulates histone acetylation, as shown in figure 1.[1] Located on chromosome band 11q23, the KMT2A gene plays a key function in embryonic and hematopoietic cell maturation. Rearrangement mutations or transcription mutations of the KMT2A protein may lead to disordered co-activator fusion or increased duplication of binding sites (partial tandem duplication [PTD]). Ultimately leading to altered epigenetic regulation has been implicated in the pathogenesis of a variety of disease states, including developmental disorders and acute leukemias.[2] Unfortunately, these mutations commonly confer a poorer prognosis to patients with acute leukemias.[1] The mutations that commonly occur with KMT2A are translocations or rearrangements, which occurs in approximately 10% of all acute leukemia cases. There have been a number of different rearrangements that have been identified to increase a patient's risk of developing, with approximately 121 different gene partners have been connected with KMT2A acute myeloid leukemia (AML). However, there are a number of mutations that are still under investigation on their specific association or risk with acute leukemias.[1,2]

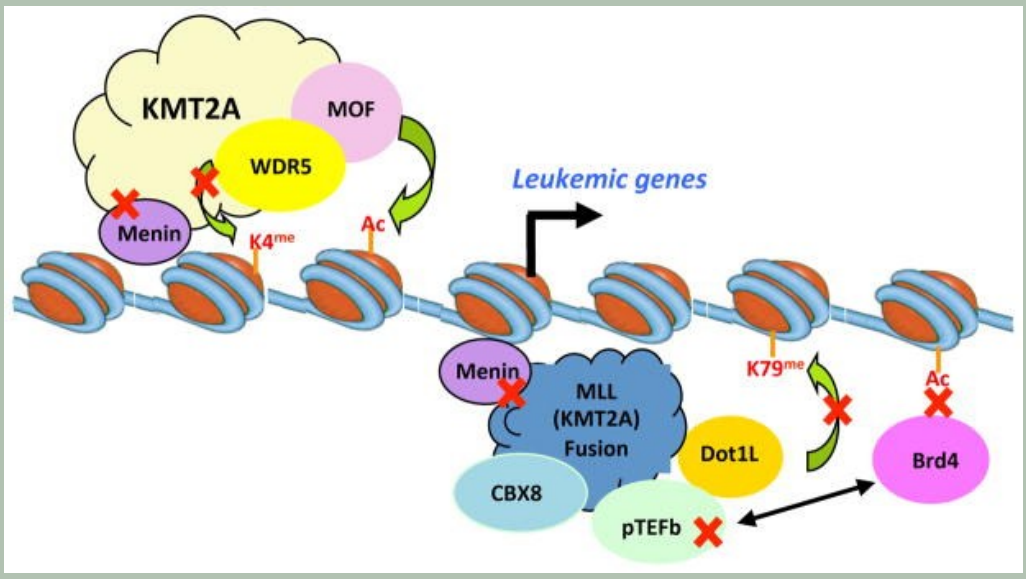


**Figure 1:** KMT2 enzymes may interact with multiple co-activators and different portions of the genome to regulate gene transcription. Mutations in KMT2A may lead to altered histone acetylation and may contribute to generation of leukemic oncogenes. The red "Xs" indicate possible small molecule targets to directly impair the underlying leukemogenic driver.[1]

Acute lymphoblastic leukemia (ALL) with KMT2A rearrangements have a wide range of incidence rates that appears to be dependent on the specific cellular subtype of ALL (B-cell vs. T-cell), as well as the age of the patient. For B-cell ALL the incidence rate appears to be between 5 and 7% of patient cases across all ages. When looking at specific age groups, patients who are infants (< 1 year old) appear to have the highest incidence of KMT2A rearranged B-cell ALL at approximately 70% of cases. The incidence in pediatric cases decreases to approximately 3% of patient cases and it increases again in adult patient cases to approximately 10%. Whereas for T-cell ALL the incidence rate appears to be approximately 8% of ALL patient cases.[2] The NCCN guidelines for ALL stratify into standard and poor prognostic risk categories, based on cytogenetic and molecular mutations identified. Patients who have ALL with any KMT2A rearrangement present are stratified to the poor risk category.[3] The most commonly identified KMT2A rearrangement in patients with B-cell ALL is t(4;11)(q21.3;q23.3). Patients with a KMT2A rearrangement appear to have a lower overall survival and higher risk of relapse compared to their matched wild type counter parts.[2,3] It appears that both pediatric and adult patients with these rearrangements have similar complete remission rates, approximately 80% to 90% for both patient populations, but the 5 year event free survival is lower at approximately 60% vs. 90% for pediatric patients, and 35% vs. 45% in adult patients.[4,5]

Switching to look at AML, the incidence rate of any KMT2A rearrangement may be up to 10% of patients, including all ages, and both de novo and secondary AML.[2] The NCCN guidelines for AML also stratify the different cytogenetic and molecular mutations into different prognostic risk categories into favorable, intermediate and poor/adverse risk. Similar to ALL, patients with AML who have a KMT2A rearrangement present have a poorer prognosis. The specific translocation associated with intermediate risk disease are t(9;11)(p21.3;q23.3) or MLLT3::KMT2A. All other KMT2A rearrangements are associated with poor risk disease.[6] While the specific mechanism behind the poor prognosis is unclear, these rearrangements appear to be more common in younger patients, < 60 years old, and those who have received prior chemotherapy. Studies have aimed to identify which agents may increase the risk, due to the relatively low number of patients with this rearrangement, it is very challenging to identify specific agents. However, cytotoxic chemotherapeutic agents, such as anthracyclines and epidophyllotoxins, may possibly increase the risk of developing KMT2A rearrangements, leading to treatment related AML. These agents mechanism of action directly interferes with appropriate DNA replication, possibly increasing their risk of secondary leukemias. The development of these KMT2A rearranged, treatment related AML appears to occur approximately 2 to 3 years after the last dose of the cytotoxic chemotherapeutic agent, which is much shorter compared to other treatment related AML states that more commonly occur approximately 10 years later.[7] A unique KMT2A rearrangement, partial tandem duplications (KMT2A-PTD), have been identified in NK-AML and has been associated with a lower overall survival if present in these patients.[8]

Patients with KMT2A rearrangements, may some unique clinical presentation features. Patients with KMT2A rearranged ALL may have high WBC (>100,000/microL) and may have a higher incidence of CNS involvement.[9] In patients with AML, they may have preceding MDS particularly if it is in the setting of treatment related AML.[6,7] As noted above, patients with acute leukemias who also have a KMT2A rearrangement have poorer outcomes compared to their wild-type counterparts, when utilizing more conventional, multiagent chemotherapy regimens following current guidelines. Due to the limited number of patients with acute leukemia who have a KMT2A rearrangement, there is little evidence on the most optimal management strategies for this unique patient population.[3,6] The possible benefit of allogeneic hematopoietic stem cell transplant (HSCT) has been investigated, but this management strategy remains an area of controversy. The evidence that shows little benefit was driven by high-risk infants with KMT2A rearranged leukemia. Whereas the evidence in older patients have failed to the show benefit of HSCT.[2] Other investigations have been pursued assessing more targeted small molecule inhibitors, such as histone deacetylase (HDAC) inhibitors and novel agent of revumenib. HDAC inhibitors have been a drug class of interest for this patient population, given the direct histone activity that they have. Currently only *in vitro* studies have been conducted, but have shown some activity towards KMT2A rearranged leukemic cells.[2] Revumenib is a novel small molecule inhibitor of menin, which has been identified as an essential oncogenic cofactor for leukemogenesis with KMT2A.[10] A recent phase 1 clinical trial has been published showing some promise for patients with KMT2A rearranged or NPM1 mutated AML, with a duration of response of 9.1 months, with 20% (9/46) of KMT2A rearranged patients achieving a complete response.[11] Additional targets are under investigation include, bromodomain inhibitors, Dot1L inhibitors, lysine-specific demethylase-1 (LSD1) inhibitors, and polycomb protein inhibitors, each of which are currently being investigated with *in vitro* studies.[2]

KMT2 is a family of genes, previously known as MLL, that utilize co-activators function as epigenetic modifiers. KMT2A specifically has been identified in embryonic cells and hematopoietic cells, and mutations have been implicated in contributing to the development in developmental disorders as well as various malignancies. Rearrangements of KMT2A in acute leukemias have been identified to promote leukemogenesis and confer a poor prognosis, compared to wild-type KMT2A. Current guidance recommend managing this subset of patients with conventional chemotherapy options. Allogeneic HSCT remains an area of interest, however current evidence is lacking in support of this treatment modality. Targeted agents, including HDAC inhibitors and menin inhibitors, are currently under investigation in an effort to directly target the underlying leukemogenic driver of KMT2A. However, further studies are warranted to guide management recommendations, and hopefully improve treatment options for this unique and high-risk patient population.

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## August 2022-February 2023

Kyle Zacholski

Bouligny IM, Murray G, Tran V, Gor J, Hang Y, Alnimer Y, **Zacholski K**, Venn C, Maher K. Real-World Safety and Efficacy of Gemtuzumab Ozogamicin in Relapsed or Refractory AML. Blood. 2022 Nov 15;140(Supplement 1):11744-.

**Zacholski K**, Hambley B, Hickey E, Kashanian S, Li A, Baer MR, Duong VH, Newman MJ, DeZern A, Gojo I, Smith BD. Arsenic trioxide dose capping to decrease toxicity in the treatment of acute promyelocytic leukemia. Journal of Oncology Pharmacy Practice. 2022 Sep;28(6):1340-9.

Julia (Lea) Ziegengeist

Lavery L, DiSogra K, **Lea J**, Trufan SJ, Symanowski JT, Roberts A, Moore DC, Heeke A, Pal S. Risk factors associated with palbociclib-induced neutropenia in patients with metastatic breast cancer. Supportive Care in Cancer. 2022 Oct 19:1-7.

## Awards
## August 2022-February 2023

**ACCP Fellow:**
Don Moore III, PharmD, BCPS, BCOP

**ACCP New Clinical Practitioner Award:**
Justin Arnall, PharmD, BCOP

**ACCP Hematology/Oncology PRN Practice Advancement Award:**
Kirollos Hanna, PharmD, BCOP

**ACCP Hematology/Oncology PRN Patient Advocate Award:**
Onyebuchi Ononogbu, PharmD, BCOP

**ACCP Hematology/Oncology PRN Emerging Member Award:**
Shawn Griffin, PharmD, BCOP