ASH Highlights and Commentary: Myeloid Malignancies

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Long Term Follow-up and Combined Phase 2 Results of Eprenetapopt (APR-246) and Azacitidine (AZA) in Patients With TP53 mutant Myelodysplastic Syndromes (MDS) and Oligoblastic Acute Myeloid Leukemia (AML)

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Introduction: TP53 gene mutations (mTP53), found in up to 20% of MDS or AML pts and 30-40% of therapy-related (TR) MDS/AML cases, represent a distinct molecular cohort with poor outcomes. Hypomethylating agents (HMA) are the frontline standard of care, with CR rates of ~20% and median OS of <12 months. APR-246 is a novel, first-in-class small molecule that reactivates the mutant p53 protein and targets cellular redox balance, ultimately inducing apoptosis and ferroptosis in mTP53 cancer cells. We previously reported the Phase 2 results of 2 parallel trials of APR-246+AZA (Sallman et al and Cluzeau et al., JCO 2021). We now report analyses of the combined Phase 2 cohorts and long-term follow-up.

Methods: This is a multicenter, international collaboration of the US MDS clinical research consortium and the GFM of HMA-naïve mTP53 higher-risk MDS, MDS/MPN and oligoblastic AML (≤30% blasts) pts (NCT03072043/NCT03588078). Pts received APR-246 4500mg IV (days 1-4) + AZA 75 mg/m² SC/IV x 7 days (days 4-10 or 4-5 and 8-12) in 28-day cycles. Primary objective was CR rate by International Working Group (IWG) 2006 criteria. Secondary objectives included ORR, OS, outcome following allogeneic hematopoietic stem cell transplant (allo-HSCT), with serial high depth next generation sequencing (NGS, 0.1% cutoff) for evaluation of measurable residual disease (MRD).

Results: As of July 15, 2021, 100 pts had been enrolled with a median age of 68 years (range, 34-87; 47% male). By WHO, 74 pts had MDS, 22 AML-MRC and 4 CML/MD-S-PMN; 83% complex karyotype (CK) and 88% were CK and/or biallelic for TP53 mutations; 92% had a TP53 missense mutation in the DNA binding domain. In 63 pts, TP53 was the only mutation detected (i.e. isolated mTP53). Median time on treatment was 6 cycles (1-25+) with 5 pts ongoing and 23 pts who proceeded to allo-HSCT. Non-hematologic treatment (Tx)-related adverse events (AEs) in ≥20% of pts included nausea/vomiting (58%), ataxia (26%), and dizziness (23%). Neurologic AEs were reversible in 100% of cases. Febrile neutropenia occurred in 37% of pts. Thirty and 60-day mortality was 1% (n=1) and 7% (n=7), respectively. Dose reductions of APR-246 and AZA occurred in 16% and 1% of pts, respectively, with only 1 treatment discontinuation due to a treatment-related AE.

By intention-to-treat (ITT) analysis, ORR by IWG was 69% with 43 CR, 1 PR, 10 marrow CR (mCR)+HI, 9 H1 alone, and 6 with mCR. Of non-responders, 6 had stable disease and 7 pts had progressive disease. The median duration of CR/PR was 10.6 months (95% CI 8.8-12.3, 23+ months ongoing). CR/PR rate for MDS was 49% (36/74),...
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36% for AML (8/22) and 0% for MDS/MPN (0/4) with an ORR rate of 70%/64%/75%, respectively. Isolated mTP53 was predictive for a higher CR rate (52% vs 30%; P=.04). Patients who had biallelic TP53 or CK had a significantly higher CR rate vs pts without (49% vs 8%; P=0.01).

On serial TP53 NGS using a VAF cutoff of 5%, 40 pts achieved NGS negativity with 6 pts MRD negative (VAF < 0.1%). Of NGS negative pts (TP53 VAF <5%), best response was CR/PR in 78% (n=31), mCR+HI in 15% (n=6), mCR in 5% (n=2) and HI in 3% (n=1). The median # of cycles in NGS negative and positive pts was 10 and 4, respectively (P<0.0001). All MRD negative pts received at least 5 cycles of therapy (5-15).

At data-cutoff by ITT analysis with a median follow up of 27.8 months, median OS was 11.8 months (95% CI 9.4-14.3). Pts undergoing allo-HSCT had a median OS of 16.1 months (95% CI 14-18.1). Impact of response and NGS clearance was evaluated by landmark analysis at 6 months. Pts achieving CR/PR or NGS negativity had improved OS (15.8 vs 10.1 months; P=0.002; Fig 1A). Additionally, pts who became MRD negative had a 2-year OS of 50% vs 23% (P=0.21). Although allo-HSCT was not predictive of OS in the overall cohort by landmark analysis (14.7 vs 14.4 months; P=0.15; Fig 1B), significant OS improvement was noted in allo-HSCT pts based on CR/PR or NGS negativity (P=0.002; Fig 1C). Notably, pts who achieved CR/PR/NGS negativity and were bridged to allo-HSCT had a median OS that was not reached (95% CI 10.4-NR) vs 9.1 months (95% CI 7.4-NR) in allo-HSCT pts who did not achieve this response (P=0.01).

Conclusions: In this international, combined analysis of P2 APR-246+AZA pts, the combination was well-tolerated with high response rates in mTP53 MDS/AML. Quality of response and NGS negativity strongly predicted OS, particularly in the setting of allo-HSCT, validating NGS clearance as a critical biomarker of allo-HSCT outcomes in mTP53 pts.
**The Advanced Practitioner Perspective:** Lindsey M. Lyle, MS, PA-C

*TP53* is a key tumor suppressor gene capable of containing cellular proliferation associated with aberrant and uncontrolled oncogene expression. *TP53* inactivation by gene mutation or deletion promotes uncontrolled proliferation of cancer cells (Molica et al., 2021). The incidence of *TP53* mutation is higher in treatment-related MDS/AML (30%-40%) than de novo MDS/AML (~20%) and represents a difficult-to-treat population. Patients with MDS or AML who harbor mutations in *TP53* often have complex cytogenetics, are of advanced age, and historically have poor outcomes, largely in part due to chemoresistance. Recent breakthroughs in AML research and the development of targeted drugs directed at specific mutations have led to a number of novel treatments.

This abstract presents long-term data from a multicenter, international, phase II trial of 100 patients with *TP53*-mutated MDS/AML treated with eprenetapopt (APR-246) and azacitidine. APR-246 has a unique mechanism of action and is a first-in-class small molecule that targets reactivating the mutant p53 protein, thereby inducing apoptosis in *TP53*-mutant cancer cells.

The primary objective was complete remission (CR) rate, and secondary objectives included overall response rate (ORR), overall survival (OS), and outcomes following allogeneic stem cell transplant. Median time on treatment was six cycles with five patients ongoing at 25 months. By an intent-to-treat analysis, the ORR was 69% with 43 patients achieving a CR, and the median duration of CR/PR was 10.6 months. Patients undergoing allo-HSCT had a median OS of 16.1 months.

**Implications for the Advanced Practitioner**

The results of this study show favorable outcomes with this combination therapy in patients with *TP53*-mutated AML/MDS. The treatment of myeloid malignancies is becoming more personalized and specific to targetable mutations and oncogenic pathways. It is important for the advanced practitioner (AP) to be aware of the potential impact of certain mutations as it relates to disease phenotype and therapeutic options.

The clearance of *TP53* mutation on serial molecular tests was found to have a significant impact on response and patients who became MRD negative had longer overall survival. Additionally, patients who were bridged to transplant after having achieved a molecular response with no detectable *TP53* mutation had better OS. This continues to support the idea that inducing a deep remission has favorable implications for our patients. The AP should understand the importance of repeat molecular testing with next-generation sequencing, especially in the pretransplant setting. This can be helpful as we discuss treatment options, the need for frequent bone marrow analysis, and methods for disease monitoring with our patients.

This combination therapy was well tolerated with few serious adverse events. In addition to gastrointestinal toxicities, dizziness and ataxia were reported in greater than 20% of patients. The study reports that the neurologic adverse events were reversible in 100% of cases, and dose reductions were rare. As APs, understanding possible side effect profiles and educating patients on these risks can help optimize successful identification, implementation of dose modifications as necessary, and continuation of therapy with proper supportive care.

Phase III trials of APR-246 + azacitidine vs. azacitidine alone in this patient population are ongoing.

**Disclosure:** Ms. Lyle has served in an advisory role for AbbVie, Bristol Myers Squibb, and Incyte.

**Reference**

Molica, M., Mazzone, C., Niscola, P., & de Fabritiis, P. (2021). *TP53* mutations in acute myeloid leukemia: Still a daunting challenge? *Frontiers in Oncology, 10.* https://doi.org/10.3389/fonc.2020.610820
Abstract 606

Efficacy and Safety of Pegcetacoplan Treatment in Complement-Inhibitor Naïve Patients With Paroxysmal Nocturnal Hemoglobinuria: Results From the Phase 3 Prince Study
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Background: Paroxysmal nocturnal hemoglobinuria (PNH) is a rare and life-threatening disease characterized by hemolysis and thrombosis. Many patients with PNH use C5-inhibitors (i.e., eculizumab/ravulizumab) to control their symptoms. Although C5-inhibition prevents intravascular hemolysis (IVH), it fails to prevent extravascular hemolysis (EVH). Because of persistent EVH, up to 72% of eculizumab-treated patients remain anemic, and up to 36% require at least one transfusion per year. Pegcetacoplan (PEG), a C3-inhibitor recently approved by the US FDA to treat adults with PNH, controls IVH and prevents EVH. Studies of PEG treatment in patients with PNH that remained anemic despite eculizumab treatment demonstrated that PEG was superior to eculizumab in achieving improvements in hemoglobin (Hb) levels (Hillmen P, et al., N Engl J Med, 2021 384 (11):1028-1037). Additionally, two early phase open-label trials demonstrated the efficacy of PEG in complement-inhibitor naïve patients with PNH (Wong RS, et al., Blood, 2020 136 [Supplement 1]).

Aims: To present results from the Phase 3 PRINCE study (NCT04085601), a multicenter, randomized, open-label, controlled study evaluating the efficacy and safety of PEG compared to standard of care (SOC; excluding complement-inhibitors) in complement-inhibitor naïve patients with PNH.

Methods: Fifty-three adult (≥18 years old), complement-inhibitor naïve (no complement-inhibitor treatment [i.e., eculizumab/ravulizumab] within 3 months prior to screening) patients with PNH and Hb levels below the lower limits of normal (males: ≤13.6 g/dL; females: ≤12.0 g/dL), and lactate dehydrogenase (LDH) levels ≥1.5 times the upper limit of normal (1.5x ULN; ≥339 U/L) were enrolled. Patients were randomized 2:1 to receive PEG (1080 mg subcutaneously twice weekly [n=35]) or SOC (excluding complement-inhibitors eculizumab/ravulizumab [n=18]) through Week 26. Patients on SOC had the option to switch to the PEG group if their Hb decreased by ≥2 g/dL from baseline. Co-primary endpoints were Hb stabilization (avoidance of a ≥1 g/dL decrease in Hb levels in the absence of transfusions) and change from baseline (CFB) in LDH level from baseline to Week 26. Secondary endpoints included CFB in Hb levels, transfusion avoidance (defined as the proportion of subjects who did not require a transfusion through Week 26), and the incidence of adverse events (AEs). Statistical analyses were performed using the Cochran-Mantel-Haenszel test and ANCOVA model.

Results: PEG was superior to SOC in both co-primary endpoints. Hb stabilization was achieved by 85.7% (n=30) of PEG-treated patients and 0.0% of SOC patients through Week 26 (p<0.0001). PEG-treated patients demonstrated superior reductions in mean LDH levels from baseline to Week 26 compared to SOC patients (least-squares mean CFB: PEG, -1870.5 U/L; SOC, -400.1 U/L; p=0.0001), and mean LDH levels in PEG-treated patients at Week 26 (mean level: 204.6 U/L) were below the ULN for LDH (226.0 U/L). PEG was also superior to SOC in the secondary endpoints: mean CFB in Hb levels (least-squares mean CFB: PEG, 2.9 g/dL; SOC, 0.3 g/dL; p=0.0019); Week 26 mean Hb: PEG, 12.8 g/dL; SOC, 9.8 g/dL (Figure) and transfusion avoidance (PEG, 91.4%, n=32; SOC, 5.6%, n=1; p<0.0001). Serious AEs were reported by 8.7% (n=4) of PEG-treated patients and 16.7% (n=3) of SOC patients through Week 26. Two deaths (PEG, 2.9%, n=1, septic shock related to medullary aplasia; SOC, 5.6%, n=1, respiratory failure), both deemed unrelated to treatment, occurred. No events of meningitis or thrombosis were reported in either group. The most common AEs reported during the study were injection site reaction (PEG, 30.4%, n=14; SOC, 0.0%), hypokalemia (PEG, 13.0%, n=6; SOC, 11.1%, n=2), and fever (PEG, 8.7%, n=4; SOC, 0.0%). There were no AEs leading to discontinuation of PEG.

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Paroxysmal nocturnal hemoglobinuria (PNH) is a rare and life-threatening disease characterized by hemolysis and thrombosis. Many patients with PNH use C5 inhibitors to control their symptoms. And while these inhibitors prevent intravascular hemolysis, they fail to prevent extravascular hemolysis. Due to persistent extravascular hemolysis, the majority of these patients remain anemic, and 36% require at least one transfusion a year.

Pegcetacoplan (PEG) is a C3 inhibitor recently approved by the FDA to treat adult patients with PNH based on meeting a number of primary and secondary endpoints. PEG has shown effectiveness in controlling both intravascular and extravascular hemolysis. Importantly, studies of PEG in patients who remained anemic while on eculizumab, a C5 inhibitor, showed that PEG was superior to eculizumab in achieving improvements in hemoglobin levels (Hillmen et al., 2021). Additionally, in two early phase trials, PEG was efficacious in complement inhibitor-naive patients with PNH. This abstract provided results from the phase III PRINCE study, which is a multicenter, randomized, open-label controlled study evaluating the efficacy and safety of PEG compared to standard of care, excluding complement inhibitors, in complement inhibitor-naive patients.

The coprimary endpoints included hemoglobin stabilization in the absence of transfusions and change from baseline (lactate dehydrogenase) LDH levels at 26 weeks. Secondary endpoints included change from baseline in hemoglobin levels, transfusion avoidance, and the incidence of adverse events.

PEG was superior to standard of care in both primary endpoints. Hemoglobin stabilization was achieved by 85.7% of PEG-treated patients, compared to 84.6% in the standard of care group. Transfusion avoidance was achieved by 46.1% of PEG-treated patients, compared to 25.4% in the standard of care group. The safety profile of PEG was similar to previous study results and represent a favorable risk-benefit profile. These results provide evidence for the safety and efficacy of PEG treatment in complement-inhibitor naïve patients with PNH.

**Conclusions:** Patients with PNH that were naïve to complement-inhibitor treatment demonstrated meaningful hematological and clinical improvements following 26 weeks of PEG treatment. The safety profile of PEG was similar to eculizumab in achieving improvements in hemoglobin levels (Hillmen et al., 2021). Additionally, in two early phase trials, PEG was efficacious in complement inhibitor-naive patients with PNH. This abstract provided results from the phase III PRINCE study, which is a multicenter, randomized, open-label controlled study evaluating the efficacy and safety of PEG compared to standard of care, excluding complement inhibitors, in complement inhibitor-naive patients.

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patients, compared with 0% in the standard-of-care arm through week 26. Additionally, PEG-treated patients demonstrated reduction in LDH with mean LDH levels below the upper limit of normal.

PEG was also superior to standard of care in key secondary endpoints, with a mean increase of hemoglobin, 2.9 g/dL in the PEG arm, resulting in a mean hemoglobin level of 12.8 g/dL at 26 weeks compared with 9.8 g/dL in the standard-of-care arm.

PEG was well tolerated, with the most commonly occurring adverse events being injection site reaction, hypokalemia, and fever. No adverse events led to the discontinuation of PEG.

Implications for the Advanced Practitioner
Excitingly, the results of this study give patients with PNH who are naive to complement-inhibitor therapy a life-sustaining option that is self-administered. PEG induced meaningful hematologic and clinical improvement at 26 weeks with increases in hemoglobin levels and a reduction in disease-related complications. The therapy appears to be well tolerated, with an adverse event profile similar to prior studies with PEG. The fact that PEG is self-administered provides greater flexibility and less time in the hematology/oncology practice, which is generally seen as a positive to the patient. As this therapy becomes more widely used, the advanced practitioner will hold an important role as it relates to promoting adherence by providing patient education about administration. Additionally, the advanced practitioner will need to identify appropriate time points for follow-up and monitoring and empower patients by educating on the potential adverse events. As with all self-administered therapies, systems need to be implemented to optimize safety and efficacy.

Disclosure: Ms. Lyle has served in an advisory role for AbbVie, Bristol Myers Squibb, and Incyte.

Reference
Hillmen, P., Szer, J., Weitz, I., Röth, A., Höchsmann, B., Panse, J.,...de la Tour, R. P. (2021). Pegcetacoplan versus eculizumab in paroxysmal nocturnal hemoglobinuria. New England Journal of Medicine, 384(11), 1028–1037. https://doi.org/10.1056/nejmoa2029073

Methods: Between 3/2021 and 5/2021, 24 hematology/oncology healthcare professionals (HCPs) from 2 large hospital systems completed surveys designed to characterize self-reported practice patterns, challenges, and barriers to collaborative MPN care. Additionally, 26 Black patients and 25 non-Black patients with MPNs completed surveys regarding their goals for treatment, barriers to care, and communication with providers. Findings from all surveys paired with patient chart data was presented to 18 HCPs from the systems in AF sessions to reflect on their own practice patterns and prioritize areas for improvement in MPN care. Participants developed team-based action plans to overcome identified challenges, including barriers in risk stratification, care coordination, and shared decision-making (SDM) for patients with MPNs. Surveys conducted before and after the small-group AF sessions evaluated changes in participants’ knowledge and confidence in delivering collaborative, patient-centered MPN care.

Results: Team-Based Surveys: HCPs identified difficulty managing their symptoms (35%)
and difficulty choosing therapy that best meets their treatment preferences and goals (25%) as the most pressing challenges their patients face in their MPN care. The most challenging issue encountered by HCPs in selecting therapies for patients with MPNs is identifying when patients are undergoing disease progression/ transformation (48%). HCPs reported effects on quality of life (75%) and treatment effectiveness (65%) as the most important factors for treatment decision-making among patients with MPNs. Teams were underutilizing SDM to provide patient-centered care, citing not enough time to engage in SDM (55%) and patients' low health literacy (50%) as the largest barriers.

Patient Surveys: In contrast to HCP responses, the biggest challenge faced in their MPN care reported by Black patients was lack of reliable transportation or long distance to and from my care center (46%) and difficulty managing my symptoms (36%) for non-Black patients. Furthermore, Black patients with MPN identified cost of treatment (56%) and advice from loved ones (40%) as the top factors for treatment decision-making, whereas non-Black patients cited how the treatment is taken (52%) and how well the treatment will control my symptoms (50%). All patients identified they wish they had more time to discuss goals and preferences for treatment (62% Black, 64% non-Black) with their provider. Black patients reported their MPN care team could improve most in education about MPNs and treatment options (73%), while non-Black patients felt improvements in empathy throughout the emotional journey of managing my MPN (68%) would be most beneficial.

Small-Group AF Sessions: Across the 2 oncology centers, teams participating in the AF sessions (Table 1) shared a self-reported caseload of 219 patients with MPNs per month. HCPs reported meaningful shifts in confidence in their ability to provide optimal, patient-centered care (Figure 1) and knowledge of treatment options for MPNs (Figure 2). The aspects of patient-centered care HCPs will routinely discuss in more detail with patients are patients' goal and preferences (81%), results of genetic testing (63%), and risks and benefits of treatment options (56%). To achieve these goals, 63% of HCPs committed to improve team skills in appropriate risk stratification and differentiation of therapy based on patient-centered factors followed by sharing action plans with additional clinical team members (56%).

Conclusions. Participation in this QI initiative resulted in increased confidence in hematology/oncology HCPs' ability to deliver patient-centered MPN care and improve commitment to team-based collaboration. Remaining practice gaps and challenges can inform future QI programs.

### Table 1. Myeloproliferative Neoplasms QI Program Participants by Clinical Role

| Team-Based Survey Respondents (N = 24) | N (%) | Audit-Feedback Session Participants (N = 18) | N (%) |
|----------------------------------------|-------|---------------------------------------------|-------|
| Medical Oncologist                     | 3 (12%) | Medical Oncologist                          | 4 (22%) |
| NP                                     | 6 (25%) | NP/PA                                       | 6 (33%) |
| Nurse/Nurse Navigator                  | 15 (63%) | Nurse                                       | 4 (22%) |
|                                        |        | Patient Navigator/Case Manager/Case Coordinator | 4 (23%) |

QI = Quality Improvement; NP = Nurse Practitioner; PA = Physician Assistant
Myeloproliferative neoplasms (MPNs) are a rare group of blood cancers including myelofibrosis, polycythemia vera, and essential thrombocythemia. Patients with MPNs suffer from a significant symptom burden and are without an abundance of effective treatment options. This quality improvement initiative used surveys from both HCPs and patients to assess barriers to patient-centered MPN care in 2 large US hospital systems. The HCPs completed surveys designed to characterize self-reported practice patterns, challenges, and barriers to collaborative MPN care. Additionally, 25 Black and 25 non-Black patients with MPNs completed surveys regarding their goals of treatment, barriers to care, and communication with providers.

Findings from all surveys were presented to the HCPs from the hospital systems in order to promote self-reflection and prioritize areas for improvement. Participants developed team-based action plans to overcome identified challenges, including barriers in risk stratification, care coordination, and shared decision-making.

The results identified differences between HCPs and patients regarding the biggest challenge in MPN care. Health-care profession-
als identified difficulty in managing patients’ symptoms (35%) and difficulty choosing therapy that best meets their treatment preference and goals (25%) as the most pressing challenges their patients face. From the patient perspective, challenges were different between the Black and non-Black population. In Black patients, lack of reliable transportation/long distance to and from the care center (46%) was the most challenging. Difficulty managing symptoms ranked the highest for non-Black patients (36%).

As it relates to treatment decision-making, the biggest influences reported by Black patients included cost of treatment (56%) and advice from loved ones (40%). In the non-Black patients, how treatment was taken (52%) and how well the treatment controlled symptoms (50%) were most important. All patients reported they wished they had more time to discuss their goals and preferences for treatment with their provider.

Based on the results of the surveys, HCPs in the study reported meaningful shifts in confidence in their ability to provide optimal, patient-centered care and knowledge about treatment options.

**Implications for the Advanced Practitioner**

There are many challenges and barriers that HCPs and patients face when it comes to cancer care. This QI initiative brought out some very important themes in how we as advanced practitioners care for our patients, and specifically in this study, patients with an MPN. We are reminded about the need for advanced practitioner-focused education on myeloid malignancies, as this will provide a solid foundation for how we implement patient education and best practices.

Not only did this study highlight the need to practice as a team, with the patient at the center of shared decision-making, but it also helps the advanced practitioner understand the patient-identified gaps and what they feel are the most important aspects of their care. It goes without saying that HCPs and patients all wish there was more time, but the results from this QI should increase confidence that when focusing on information most desired by our patients, we can be efficient with our visits.

**Disclosure:** Ms. Lyle has served in an advisory role for AbbVie, Bristol Myers Squibb, and Incyte.