Q: HOW DID YOUR JOURNEY BEGIN?

A: My journey began with a simple, routine blood work visit. My primary doctor said to go back to the lab ASAP because my platelet number couldn’t be right and that sometimes that test is inaccurate. He said that my platelets were a crazy whacked out number that couldn’t be correct. It was 985 and turned out to be correct...He sent me to a hematologist.

Q: WHAT IS YOUR DIAGNOSIS?

A: I was diagnosed with essential thrombocytosis in August of 2012 and tested positive for the JAK2V617F mutation.

Q: WERE YOU DIAGNOSED CORRECTLY FROM THE START? IF NOT, WHAT HAPPENED?

A: It has been a rough road for me since the beginning of my diagnosis. It was correct. They at least knew I was JAK2 positive, but what to do with me? That was another matter. The first of several doctors I sought treatment with looked afraid and declared to my sister “this is an emergency! I am prescribing anagrelide and you must take a larger dose the first day and get that level down...also make an appointment at Mayo or Cleveland clinic ASAP.” He was very alarming! At this point I had only had ocular migraines but felt fine in general...this was to change for me (feeling fine). The anagrelide affected me so strongly a few hours after taking it that I had to go to the ER. My heart started going off rhythm. At the hospital, they started injecting me every four hours with a strong blood thinner (I learned later that this could have caused hemorrhaging due to our immature blood platelets). The same doctor then tried me on hydroxyurea, which had an even worse effect. I tried this drug at 500 mg and was allergic (for want of another word that would properly describe the reaction). I tried to take it with allergy medicine and it still had the same effect. I felt as if I could not breathe. They then tried me on 200 mg of hydroxyurea, and this culminated with me getting extremely ill. I could not breathe. I felt as if someone had heated my blood, and this hot blood was circulating through my heart. I would also get dizzy and my vision got blurry. All of this required another trip to the ER. At the ER, the doctor there said my body could not tolerate the hydroxyurea. It seemed that not only was I not tolerant of these drugs, but that it sent my symptoms through the roof. My platelet count went up to 1,265 and I had a three day spell of not being able to pull in enough oxygen to carry on normal conversations. Apparently, this happens when you remove a platelet reduction med or have apheresis—your platelets will go haywire. At this

[continued on page 3]
Happy 2017! In 2016, we saw a focus on clinical studies in polycythemia vera (PV). Two phase 3 studies investigated the role of pegylated interferons as therapy for PV, and we have highlighted results from those studies in this issue.

In addition, there is a growing awareness of “masked PV,” where patients present with signs and symptoms of PV but with hemoglobin levels that do not meet the 2008 World Health Organization (WHO) criteria for PV (Hg > 16.5 g/dL for women and Hg > 18.5 g/dL for men). The new criteria published by WHO in 2016 have lowered the hemoglobin levels to > 16.5 g/dL in men and > 16 g/dL in women. In addition, bone marrow morphology is now a major criterion, whereas before it was only a minor criterion.

These changes should help physicians recognize and properly diagnosis PV, and longer-term studies of pegylated interferon will hopefully improve treatments for PV as well. In this issue we also summarize the most important clinical findings of 2016, which were presented in December at the American Society of Hematology Annual Meeting in San Diego.

Dr. Srdan Verstovsek, Professor of Medicine in the Department of Leukemia at MD Anderson Cancer Center, serves as Director of the Hanns A. Pielenz Clinical Research Center for Myeloproliferative Neoplasia. Dr. Verstovsek is an internationally recognized physician scientist dedicated to understanding the biology of and developing new therapies for MPNs.

Support for Patients in Texas

Founded by MPN patient and advocate Charlie Nielsen, the South Texas support group meets several times a year to discuss issues associated with living with an MPN.

The North Texas support group is led by Andrea Spica and meets quarterly.

Both groups provide an opportunity to meet and share with others who have a similar diagnosis.

To find out more information or join either group, please contact them either by e-mail or through their Facebook page:

North Texas, Dallas/Ft. Worth
Andrea926@SCGlobal.net

South Texas, Houston
CharlieNielsen@aol.com

Facebook
Facebook.com/groups/MPNSupportTX
Spotlight

time my doctor wanted to have an apheresis procedure done on me. I turned them down and escaped the hospital… I decided to check with a doctor based in Miami who told me that my condition does not need to be treated unless my platelet level goes above 1,500 and that all I needed was two low-dose aspirins a day. So all of the previous treatments and ER visits were completely unnecessary. In addition, it was my first year as a lead teacher in the public school system, and I missed a ton of work as well as many days with no pay and thousands of dollars in hospital and medical bills. The aspirin immediately took away the migraines and dizzy spells. I just needed a local doctor who would be on board with the correct treatments. In efforts to find a doctor nearer home (Miami is 2 hours away), I visited two other hematologists who were clueless about how to treat an ET patient. One doctor told me that with my condition people only live 15 to 20 years, which had me very worried. Since that time, Dr. Pimentel in Miami told me that ET patients live a normal life span as long as I am monitored and considers me in the low risk category (the risks increase after age 60 or if my platelets reach the 1,500 level). I have now found a wonderful local doctor who has a calm and non-frightening demeanor, and I appreciate her so much. She is eagerly awaiting input from MD Anderson when I see Dr. Verstovsek this summer. My platelet level is currently 1089.

Q: DID YOU FIND IT DIFFICULT TO COPE WITH YOUR DIAGNOSIS?
A: Yes. I think the difficult part for me is having something so rare. I don’t trust local doctors in the event something out of the ordinary happens with my condition. I know that if I have any surgery I have to have my platelets reduced with apheresis and I wonder…what would happen in an emergency? Like a car crash? Also walking around with that high platelet level makes you worry every day that a clot could form, or you could suffer a stroke or heart attack. I really would love to have a less scary platelet level. It is hard when I tell people about my condition. I have learned to omit the cancer word because each time whoever I’m talking to will grow silent and look uncomfortable as if they don’t know what to say.

Q: IN WHAT WAYS HAS YOUR LIFE CHANGED SINCE BEING DIAGNOSED?
A: I look out after my health more. I used to overdo it and think I was invincible. I’m a single mom and would often take on too much. Now I pamper myself more. I have to admit that the diagnosis took a good dose of joy away from me and added a good dose of fear.

Q: WHAT ARE SOME OF THE DIFFICULTIES YOU FACE?
A: I will occasionally experience chronic fatigue from ET if I push too hard and let myself overdo it. I also have linked stress to this reaction.

Q: WHAT IS SOMETHING POSITIVE THAT HAS COME FROM YOUR DIAGNOSIS?
A: You appreciate life more and realize what is really important and what is not. People think they have some big tragedy because a family member is mad at them, or they think they look fat, etc...lol! Well I would take many, many of the negative things that people feel they are absolutely devastated about over having to live each day with a rare blood crud. This is my safer and less scary, funny nickname for ET that I use to share with the world. One that makes doctors look like a deer in the headlights and each and every one of them has a different idea of what to do with you...some different ideas that can kill you or send you for multiple hospital visits.

Q: WHAT IS SOMETHING THAT YOU HAVE LEARNED SINCE BEING DIAGNOSED THAT YOU WOULD LIKE TO SHARE WITH THE WORLD?
A: Gain knowledge. Seek out and have an appointment with an MPN specialist. I plan to do that this summer. So you can have a medical GPS for the doctors you see locally to keep you safe and alive and living a full lifespan.

Gifts provide critical support needed to conduct innovative MPN research. Our MPN clinical and laboratory research team is dedicated to improving treatment outcomes for patients with MPNs.

To make a donation by mail, please send gifts to The University of Texas MD Anderson Cancer Center and specify “MPN Clinical Research Center” in the memo line using the attached envelope.
Phase 2 Study of INCB050465 in Combination with Ruxolitinib in Patients with Myelofibrosis
2016-0233 (NCT No: NCT02718300)
Principal Investigator: Naval Daver

Study Description: The goal of this study is to determine the highest tolerable dose of INCB050465 that can be given in combination with ruxolitinib to patients with myelofibrosis. The effect of this drug combination on spleen size and myelofibrosis symptoms will also be studied. INCB050465 is a PI3Kδ inhibitor that may improve the efficacy of ruxolitinib. Patients who have been treated with ruxolitinib for at least 6 months and on a stable dose for at least 8 weeks are eligible. This study is currently enrolling patients.

Phase 2 Study of Nivolumab in Patients with Myelofibrosis
2014-0962 (NCT No: NCT02421354)
Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to determine the effectiveness of nivolumab in patients with myelofibrosis. The safety of this drug will also be tested. Nivolumab is a treatment that uses your immune system to treat disease. Patients will receive nivolumab intravenously every 2 weeks for at least 8 doses and then every 3 months thereafter.

Phase 2 Study of Ruxolitinib and Pracinostat in Patients with Myelofibrosis
2014-0445 (clinicaltrials.gov NCT No: NCT02267278)
Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to determine the effectiveness of the combination of ruxolitinib and pracinostat in patients with myelofibrosis. The safety of this drug combination will also be studied. Pracinostat is a histone deacetylase inhibitor. Patients will receive ruxolitinib orally as a single agent for the first 3 months, after which point oral pracinostat will be added. This study is accepting patients with myelofibrosis who have not been previously treated with a JAK inhibitor. Study visits will be monthly for the first 6 months and then every 3 months thereafter.

Phase 2 Prospective, Open-Label Study of Sotatercept (ACE-011) in Patients with Myelofibrosis and Significant Anemia
2012-0534 (clinicaltrials.gov NCT No: NCT01712308)
Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to learn if sotatercept can help to control anemia in myelofibrosis. The safety of this drug will also be studied. Sotatercept (ACE-011) may increase the growth and development of red blood cells. Patients will be given subcutaneous injections once every 3 weeks for at least 6 months. This study is accepting patients with myelofibrosis and significant anemia, including those who have been taking ruxolitinib for at least 3 months.

Phase 2 Study of Eltrombopag in Patients with Symptomatic Myelofibrosis on Low-Dose Ruxolitinib Due to Low Platelet Count
2011-0319 (clinicaltrials.gov NCT No: NCT01428635)
Principal Investigator: Gautam Borthakur

Study Description: The goal of this study is to learn if eltrombopag can help control or prevent low platelet counts in patients receiving ruxolitinib for myelofibrosis. Eltrombopag is a protein that binds a molecule on blood cells that controls the production of platelets. Patients will continue taking ruxolitinib as prescribed, but will also take eltrombopag as a pill once per day. This study is currently accepting patients with myelofibrosis and low platelet counts.

Phase 2 Study of LCL-161 in Patients with Myelofibrosis
2013-0612 (clinicaltrials.gov NCT No: NCT02098161)
Principal Investigator: Naveen Pemmaraju

Study Description: The goal of this clinical research study is to learn if LCL-161 can help to control anemia in myelofibrosis. The safety of this drug will also be studied. LCL-161 is an oral drug that activates a signaling pathway that promotes cancer cell death. Patients will receive LCL-161 orally every 7 days. Study visits will be monthly for the first 4 months and then every 3 months thereafter.

Listed below are all open clinical trials enrolling patients with MPNs at MD Anderson Cancer Center as of February 15, 2017. For more information on these clinical trials, call the information line toll-free at 1-800-392-1611 or contact Dr. Verstovsek at sverstov@mdanderson.org. For information on other clinical trials in MPN go to clinicaltrials.gov.
Phase 1 Study of BLU-285 in Patients with Advanced Systemic Mastocytosis or Relapsed or Refractory Myeloid Malignancies

2015-0832 (clinicaltrials.gov NCT No: NCT02561988)

Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to determine the highest tolerable dose of BLU-285 that can be given to patients with advanced systemic mastocytosis or relapsed/refractory myeloid malignancies. The safety and efficacy of this drug will also be studied. BLU-285 is an oral drug that is designed to block the activity of the mutated form of the KIT receptor tyrosine kinase (KITD816V), which is present in patients with systemic mastocytosis. Patients will receive BLU-285 orally once daily. This study is currently enrolling patients with advanced systemic mastocytosis, mast cell leukemia or another myeloid malignancy that has relapsed or is not treatable by standard treatments.

Phase 1/2 Study of SL-401 in Patients with Advanced, High-Risk MPNs, Including Myelofibrosis, Chronic Myelomonocytic Leukemia, and Hypereosinophilic Syndrome/Chronic Eosinophilic Leukemia

2014-0976 (clinicaltrials.gov NCT No: NCT02268253)

Principal Investigator: Naveen Pemmaraju

Study Description: The goal of this study is to study the safety and efficacy of SL-401 in patients with high-risk MPNs. SL-401 is a biological agent that binds to cells that cause MPNs. Patients with symptomatic myelofibrosis who are not candidates for, are intolerant of or have failed therapy with ruxolitinib are eligible. Patients with chronic myelomonocytic leukemia or primary eosinophilic disorders who are not candidates for therapy with imatinib are also eligible. SL-401 will be given intravenously daily for the first 3 days of each 28-day cycle.

Prospective Evaluation of Ruxolitinib for Chronic Neutrophilic Leukemia/Atypical Chronic Myeloid Leukemia Patients with Mutation of CSF3R

2014-0764 (clinicaltrials.gov NCT No: NCT02092324)

Principal Investigator: Jorge Cortes

Study Description: The goal of this study is to learn about the effects ruxolitinib has on patients with chronic neutrophilic leukemia or atypical chronic myeloid leukemia. The safety of this drug will also be studied. Ruxolitinib is drug that blocks the activity of JAK2 tyrosine kinase, an enzyme in bone marrow cells that drives their growth. Patients will receive ruxolitinib orally twice daily for 24 months. Study visits will be weekly for the first month and then every 2 weeks thereafter.

Phase 2 Study of INCB54828 Patients with Myeloid/Lymphoid Neoplasms with FGFR rearrangement (8p11 translocation)

2016-0635 (NCT No: NCT03011372)

Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to determine the efficacy of INCB054828 in patients with myeloid/lymphoid neoplasms and with fibroblast growth factor receptor (FGFR) rearrangements. The safety of this drug will also be studied. Patients with a myeloid or lymphoid neoplasm with 8p11 rearrangement who have not previously been treated with an FGFR inhibitor are eligible. Patients will receive INCB054828 once daily for 2 weeks followed by 1 week off therapy for each cycle. This study will begin enrolling patients in the next few months.

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TO SCHEDULE AN APPOINTMENT CALL 1-85-LEUKEMIA (TOLL-FREE) OR 713-563-2000
RESULTS OF THE PHASE 3 PROUD-PV STUDY COMPARING ROPEGINTERFERON ALFA-2B WITH HYDROXYUREA IN PATIENTS WITH POLYCYTHEMIA VERA
Gisslinger H et al. Blood 128:475

Ropeginterferon (ropeg) is a modified version of interferon-alfa. Although smaller studies have been done, this was the first and largest controlled trial of interferon in PV. Patients with PV (n=257) who needed cytoreduction or had been treated with hydroxyurea (HU) for < 3 years were randomized to either ropeg (n=127) administered once every 14 days or HU (n=127) taken daily. The primary objective of the study was to demonstrate that ropeg was not less effective than HU. After 12 months of treatment, 43% of patients who received ropeg had a complete hematologic response compared with 46% of those who received HU. Side effects were less common in patients treated with ropeg (60% vs 76% HU). These findings confirm that ropeg is not inferior to HU and may be associated with fewer side effects. The study is continuing to examine the long-term effects of both drugs.

PHASE 3 STUDY OF PEGYLATED INTERFERON ALFA-2A (PEGASYS) VERSUS HYDROXYUREA IN HIGH-RISK ET OR PV
Mascarenhas JO et al. Blood 128:479

Pegasys is another modified version of interferon-alfa. This study compared the rate of complete hematologic response (CR) in patients with high-risk ET or PV who were treated with either Pegasys (n=36) once weekly or HU (n=39) once daily. After 12 months of therapy there was no difference in the CR rates between groups: 33% of those treated with HU versus 28% of those with treated with Pegasys. Only one patient in each arm discontinued treatment due to side effects. This study is continuing to examine whether there are differences in outcomes after long-term treatment.

PHASE 3 STUDY OF PACRITINIB VS BEST AVAILABLE THERAPY (BAT) IN MYELOFIBROSIS PATIENTS WITH PLATELET COUNTS < 100 X 10^9/L

Pacritinib is an oral kinase inhibitor that is less likely to cause anemia or thrombocytopenia. This is important because ruxolitinib cannot be used in patients with very low platelet counts. This study compared the efficacy of pacritinib and best available therapy (BAT) (most commonly ruxolitinib or HU). Of the 311 patients that enrolled 107 received 200 mg pacritinib twice daily; 104 received 400 mg pacritinib...
Once daily; and 100 received BAT. After 24 weeks of treatment, 18% of patients treated with pacritinib had a ≥35% reduction in a spleen volume compared with 3% of those who received BAT. In addition, 25% of patients treated with pacritinib had a ≥50% reduction in the total symptom score compared with 14% of those in the BAT arm. The lower dose (200 mg) taken twice daily was more effective than 400 mg taken once daily. In February 2016, the FDA had placed the trial on a clinical hold to investigate concerns about bleeding and cardiovascular side effects. However, as of January 2017, the FDA had removed the clinical hold, allowing the trial to continue.

PHASE 2 STUDY OF SOTATERCEPT (ACE-011) IN MYELOPROLIFERATIVE NEOPLASM-ASSOCIATED ANEMIA.


Sotatercept (ACE-011) is a drug that helps to control anemia in myelofibrosis patients. The drug acts by increasing the growth and development of red blood cells. Nineteen patients with persistent anemia were enrolled and received sotatercept as a subcutaneous injection once every 3 weeks. Of 14 patients who were evaluable for a response, 5 (36%) had a ≥1.5 g/dL increase in hemoglobin that was sustained for at least 3 months. The drug was well tolerated and the study is ongoing and enrolling patients. In addition, patients who have been taking ruxolitinib for at least 3 months and are still experiencing anemia are now eligible to enroll.

FIVE-YEAR SURVIVAL ANALYSIS OF PATIENTS WITH MYELOFIBROSIS TREATED WITH RUXOLITINIB IN THE COMFORT-I AND COMFORT-II TRIALS


Overall 528 patients were enrolled in the COMFORT studies (301 ruxolitinib; 227 placebo). All patients in the placebo arm had switched to ruxolitinib by 3 years. After 5 years, patients in the initial ruxolitinib group had a longer survival than those initially in the placebo group. Also patients with intermediate-2 or high risk myelofibrosis who were initially treated in the ruxolitinib group had longer survival than those who started in the placebo group. These findings suggest that earlier treatment with ruxolitinib may improve survival for patients with myelofibrosis.

RUXOLITINIB IN COMBINATION WITH 5-AZACYTIDINE IN PATIENTS WITH MYELOFIBROSIS

Daver N et al. Blood 128:1127

Azacytidine is a hypomethylating agent with modest efficacy in myelofibrosis. This study combines azacytidine with ruxolitinib as a strategy to improve the efficacy of both drugs. Patients received ruxolitinib twice daily for the first 3 cycles. Starting with cycle 4, patients received azacytidine intravenously daily for 4 days every 4-6 weeks. Of 39 patients, 28 (72%) had some type of response (reduction in palpable spleen length, reduction in symptoms, or improvements in anemia). Forty-eight percent of patients had a ≥50% reduction in palpable spleen size at 24 weeks and 79% at any time during the study. 79% of patients had stable or improved bone marrow fibrosis, and 63% had some reduction in JAK2 allele burden. The combination was well tolerated and only 1 patient discontinued due to low blood counts. The study is ongoing and still enrolling patients.

PHASE I STUDY OF RUXOLITINIB IN COMBINATION WITH A PI3Kδ INHIBITOR (TGR-1202)

Moyo T, Savona M et al. Blood 128:1125

PI3Kδ is a protein found at high levels in patients with myelofibrosis. This study evaluated the maximum tolerated dose, safety and efficacy of TGR-1202 (a PI3Kδ inhibitor) in 11 patients with myelofibrosis who had a suboptimal response to ruxolitinib. Patients received TGF-1202 daily along with their usual dose of ruxolitinib. Anemia was the most common side effect. Of 9 patients who were evaluable for a response, 1 achieved a complete remission and 7 had stable disease. In addition, 7 patients had improvements in blood cell counts and 8 had reductions in symptoms. Further studies of this combination are being planned.

PHASE I STUDY OF BLU-285 IN PATIENTS WITH ADVANCED SYSTEMIC MASTOCYTOSIS

Drummond M et al. Blood 128:477

BLU-285 is a KIT inhibitor that is specific for the mutated version of the protein (KIT D186V), which is found in 90-95% of patients with systemic mastocytosis (SM). Patients with aggressive SM (n=15), SM with an associated hematologic disorder (SM-AHN) and at least one C-finding (n=15), or those with mast cell leukemia (n=5) received BLU-285 orally once daily. The objective of the study was to determine the maximum tolerated dose of BLU-285. Data from 12 patients were analyzed. Mild fatigue and anemia were the most common side effects. An initial increase in alkaline phosphatase occurred in 3 patients but was not associated with symptoms and returned to normal levels after 2 cycles. Ten of 12 (83%) patients had a reduction in tryptase levels, and 63% (5/8) of those with a high percentage of mast cells in the bone marrow had reductions in mast cells. Ten (83%) of the patients remain on the study and will continue to be treated. This study is ongoing and still enrolling patients. •
MPN Focus is a periodic newsletter published by The Hanns A. Pie lenz Clinical Research Center for Myeloproliferative Neoplasia at MD Anderson Cancer Center to provide members of the MPN community with information on current research and treatments.

Editor: Kate J. Newberry, Ph.D.
For questions, comments or to subscribe, please contact Kate Newberry at kinuxber@mdanderson.org

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**Resources FOR PATIENTS**

**MPN Advocacy & Education International**

- **2017 Patient Education Symposia** hosted by MPN Advocacy & Education International
  - March 30, 2017 in Novi, Michigan
  - April 28, 2017 in Melbourne, Australia
  - June 9, 2017 in Cleveland, Ohio
  - September 29, 2017 in Los Angeles, California
  - October 26, 2017 in Atlanta, Georgia
  - November 10, 2017 in Washington, DC

For more information visit mpnadvocacy.com or contact Ann Brazeau at 517-889-6889 or abrazeau@mpnadvocacy.com.

Founded by Ann Brazeau, former vice president of development at MPN Research Foundation, MPN Advocacy & Education International provides educational programs, materials, and resources for patients, caregivers, physicians, and entire healthcare teams to improve their understanding of MF, PV, and ET.

**MPN Education Foundation**

Formed in 2004, the MPN Education Foundation aims to bring information, reassurance and support to MPN patients and their loved ones all over the world via a website (mpninfo.org), by convening a patient conference every 2 years, and via the email-based support group MPN-NET.

**MPN-NET** is an email-based support group formed in 1994 by patient Joyce Niblack. In May of 1996 the group became a member of the Association of Cancer Online Resources, distributing email via a listserv platform. Although MPN-NET remains a US-centric organization, the group has nearly 2900 members from around the globe. All discussions since its inception in May 1996 are archived and available to all members. You can subscribe to MPN-NET on Foundation’s homepage at mpninfo.org.

**MPN Cancer Connection**, also founded by David Wallace, is a non-profit “patient-focused” organization that helps educate and empower MPN patients by providing the necessary resources and funding for PV Reporter. For more information or to subscribe to their newsletter visit mpncancerconnection.org.

**MPN Research Foundation**

Founded by patients for patients, the MPN Research Foundation is a catalyst for research funding in pursuit of new treatments – and eventually a cure – for MPNs. To date, they have funded more than $11 million in MPN research. They are also dedicated to helping patients change their prognosis by serving as a valuable source of education and resources in the MPN community. mpnresearchfoundation.org

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**APFED** is a non-profit patient advocacy organization established to assist and support patients and their families coping with eosinophil associated diseases (EADs), including eosinophil-associated gastrointestinal disorders, hypereosinophilic syndrome, and Churg-Strauss Syndrome. For more information go to apfed.org.

**The Mastocytosis Society, Inc.** is a non-profit organization dedicated to supporting patients with mastocytosis and mast cell activation disorders, as well as their families, caregivers and physicians through research, education and advocacy. tmsforacure.org

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**PV Reporter.com** is a comprehensive, easy-to-navigate, patient-focused website for MPNs developed by David Wallace, "an aspiring web designer, publisher, writer, patient advocate," who was diagnosed with polycythemia vera in 2008. PVReporter.com was created to provide “easy access” to pertinent information on PV, ET, and MF. For more information visit pvreporter.com.

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MPN Focus