

MPN Focus



February, 2013 I was told that my chronic polycythemia vera (PV) had converted to an aggressive form of myelofibrosis (MF).

1 Ticket to Ride the Rollercoaster from MPNs through SCT

By Marina Sampanes Peed
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February, 2013 I was told that my chronic polycythemia vera (PV) had converted to an aggressive form of myelofibrosis (MF). I would soon become transfusion dependent and would need a donor hematopoietic stem cell transplant (SCT) within the year. Wow! My mind was swirling ~ is this real? I don't have time for

this. My daughter was a high school senior and my son was a junior. Couldn't it wait until Alexander went off to college? The doctor said, "I don't think you have that much time. The healthier you are going into transplant, the better your outcome."

Fortunately, this consultation was hours before the start of the biennial MPN Patient Conference hosted by the MPN Education Foundation and Mayo Clinic Scottsdale. My mother and I came from Atlanta for this expert consultation and conference. We knew my health was declining, but neither of us expected this.

I looked forward to seeing MPN friends I met at the 2011 conference and many I got to know through on-line patient support communities. These are people who understand. When they say "you look great!" they aren't dismissing what I'm feeling or what is going on in my bones. No annoying, judgment-laden questions. No ridiculous advice.

So when I exchanged greetings with the first person I recognized and he asked "How are you?" I blurted out, "Dr. Mesa just told me I need a transplant this year." Then came hugs. And introductions to transplant survivors. It was the best weekend I could hope for.

This might sound strange, but along with the shock of hearing that my illness had become terminal, I experienced an odd sense of relief. I was now eligible for a chance for a cure of all that I've experienced since the MPNs disrupted my life.

I was trapped in a body that had gone awry with no cure in sight. Over six years, my body was changing in ways that puzzled every specialist I met. Being "a special case" or "a complex case" or "ahead of current science" was not comforting when in chronic pain. Let me explain.

In a few short years, I went from leading a medium-sized nonprofit housing organization and active in many community organizations to being unpredictably functional physically and mentally. My life was turned upside down in 2007 with emergency surgery for a thrombotic mesentery assault. The thrombosis in three veins caused significant damage from which I never fully recovered. The PV diagnosis was made in 2009 when my hematocrit was 69 and I had a host of untenable symptoms.

The fun continued in 2010 when Behcet's Disease, a rare auto-immune illness, joined my list of chronic maladies. The Behcet's caused excruciatingly painful inflammation and lesions in mucosal regions (the mouth and "down south"). It was a diagnosis by exclusion. Sometimes the side effects of the medications were worse than the ailments they treated.

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Letter from the Director



Each day I am encouraged, as we continue to make progress in understanding and treating MPNs. While the JAK inhibitors have significantly improved the treatment options for patients with myelofibrosis and now those with polycythemia vera, we know that they are not a cure. Therefore, the search continues for novel therapies for patients with MPNs. One exciting strategy that is being tested in clinical trials is to combine ruxolitinib with other agents. The goal of this strategy is to improve upon the effects of ruxolitinib and to provide additional benefits, for example, a reduction or stabilization in bone marrow fibrosis, or improvement in anemia. Several combinations that are now being tested in clinical trials include pracinostat + ruxolitinib (NCT02267278), panobinostat + ruxolitinib (NCT01693601), azacytidine + ruxolitinib (NCT01787487), decitabine + ruxolitinib (NCT02076191), and ruxolitinib before stem cell transplantation (NCT01790295).

Beyond the JAK inhibitors, some exciting new therapeutic strategies are also emerging. One of these is a novel strategy that uses the body's own immune system to fight cancer. Nivolumab, a novel immune checkpoint inhibitor, has induced remissions in patients with advanced-stage melanoma and non-small cell lung cancer. We have recently opened a clinical trial testing nivolumab in myelofibrosis, and in this issue, we provide an overview of immunotherapy and how it may be applied to myelofibrosis. Other new therapies that target other cell signaling pathways are also being tested. A drug that targets the Hedgehog signaling pathway is currently being tested in a phase 2 clinical trial (PF-4449913; NCT02226172). For more information on these and other clinical trials for MPNs you can visit www.clinicaltrials.gov and search for information using the NCT number.

An important goal of our Clinical Research Center is to provide additional therapeutic options for our patients.

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.



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1 Ticket to Ride the Rollercoaster from MPNs through SCT

I took on this SCT challenge the way I approach any other project: begin with the end in mind. Research options, gather information, and weigh trade-offs. Make the best decision with the information available. Go for it. No regrets.

The first step was to find a donor. When none of my four siblings were a marrow match, my fate was in the National Marrow Donor Registry. My family and friends held "swab drives" to get more healthy people to join the registry (2,000 so far, with 6 life-saving matches). While I didn't find my match in the US, my lifesaver was a 22 year old man from Germany.

Next first step: decide where to have the transplant. This was a combination of researching outcomes (which is not easy with myelofibrosis cases), navigating insurance and cost issues, and family considerations. I was very fortunate that Northside Hospital & the Blood & Marrow Transplant Group of Georgia met my needs. Insurance covered most (yay!), their outcomes are excellent, they have experience with myelofibrosis, and it uses

an out-patient protocol. It's 25 miles from home, so we could make the daily drive to the clinic (next to the hospital).

With the basic plan in place, it was important that my family and friends could talk to me and one another without whispering words like 'cancer' and 'transplant.' So I had a brunch at my home with my mom and a few close girlfriends. There, my talented hair stylist friend shaved my head. We all laughed, traded wisecracks, and shared a few tears.

Before the transplant, I was given a notebook full of information that included a "Typical 100 day Timeline." It triggered disappointment and doubt when my progress was VERY far behind. The myelofibrosis causes a lot of damage in the bones and it took several months longer for my donor's stem cells to make themselves at home and get to work. I also had ABO incompatibility issue which prevented my donor's A+ reds to overcome my antibodies (I was B- type). It took one year for Wolfie's red cells to take over production.

for nausea and pain meds but reluctant to ask for help when our brain goes haywire? I experienced depression, mania, and psychosis due to some of the treatments and fortunately got help when I asked for it.

Eighteen months after my SCT (January, 2015), I heard the wonderful word, "Remission." I'm still catching up on my childhood vaccinations and need IVIG monthly. But overall I feel the best I've felt in 10 years! It's quite humbling to receive this gift of life and good health. In addition to my stem cell donor, my life depended on the generosity of strangers for the 200+ units of red blood cells and 100+ units of platelets I needed over a year and a half.

I remain thankful to all who made this possible and commit that their efforts and investments are not in vain. I will 'pay it forward' and advocate for patients and all the great work to bring more cure options to MPN patients. I still claim "chemo brain" when it suits me, but it could just be a sign that I'm almost 50. This July I celebrate my 50th birthday and 2nd Re-birthday. It's going to be my best decade yet!



The Sunday before starting chemo, we had a "Chemo Kick-off" party with family and friends, including our kids' friends and their parents. A henna artist drew on my head and did artwork on our guests. My son and a few male friends shaved their heads in solidarity. We laughed, we talked, we prayed. I told them, "You are our tribe. There is a long journey ahead and I'm told it's quite a roller coaster. Thank you for joining us."

On July 26, 2013, I received Wolfie's life-saving stem cells at Northside Hospital in Atlanta. (We gave my donor a made up German sounding name because "donor" doesn't sound as personal as his gift is to me.) And that's when the real fight began.

I had liver GvHD that put me in the hospital and also gave me a month on super-steroids that made me psychotic (really!). I also had a mean gall bladder that caused problems and had to be removed. Between the transplant and portal hypertension from the PV-caused thrombosis, they called in a transplant surgeon who has experience with organs wrapped in varices.

I was warned that the emotional toll is harder than one anticipates. For many of us, this is the first thing in our lives that we aren't able to push through by sheer will-power. Problems arise with no clear-cut solutions; everything has a trade-off. We have to trust the medical team to decide for us. Why are we comfortable asking



MPN Clinical Trials

Listed below are all open clinical trials enrolling patients with MPNs at MD Anderson as of May 15, 2015. For more information on these clinical trials, call the information line toll-free at 1-800-392-1611. For information on other clinical trials in MPN go to www.clinicaltrials.gov.

Phase 2 Study of Nivolumab in Patients with Myelofibrosis

2014-0962

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 8 doses and then every 3 months thereafter.

Phase 3 Randomized Study of Oral Pacritinib vs. Best Available Therapy in Patients with Thrombocytopenia and Myelofibrosis

2013-1001 (clinicaltrials.gov NCT No: NCT02055781)

Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to compare the effectiveness of 2 different dose schedules of pacritinib to standard treatments in patients with myelofibrosis (MF). Pacritinib is an oral drug that inhibits the activity of JAK2, but does not worsen thrombocytopenia, suggesting it may be a better alternative for treating patients with low platelet counts. Study visits will be every week for the first month and then once per month up to week 24. After 24 weeks, patients receiving best available therapy will receive pacritinib.

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 MF. 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 MF who have not been previously treated with a JAK inhibitor.

Phase 3 Randomized, Double-Blind Study of Momelotinib vs Ruxolitinib in Patients with Myelofibrosis

2013-0741 (clinicaltrials.gov NCT No: NCT01969838)

Principal Investigator: Srdan Verstovsek

Study Design: The goal of the study is to compare the effectiveness of momelotinib to ruxolitinib in patients with myelofibrosis. Momelotinib is an oral JAK2 inhibitor. Patients will be randomized to receive either momelotinib orally once daily plus ruxolitinib placebo twice daily or ruxolitinib orally twice daily plus momelotinib placebo once daily for at least 24 weeks. Study visits will be every 2 weeks.

Phase 3 Randomized, Double-Blind Study of Momelotinib vs Best Available Therapy in Patients with Anemia or Thrombocytopenia and Myelofibrosis Who Have Been Previously Treated with Ruxolitinib

2014-0258 (clinicaltrials.gov NCT No: NCT02101268)

Principal Investigator: Srdan Verstovsek

Study Description: The goal of this study is to compare the effectiveness of momelotinib to standard treatments in patients with myelofibrosis. Momelotinib is an oral JAK2 inhibitor. Patients will be randomized to receive either momelotinib orally once daily or best available therapy. Study visits will be every 2 weeks for at least 24 weeks. After 24 weeks, patients receiving best available therapy will receive momelotinib.

Phase 2 Double-Blind, Randomized Study of PF-0444913 vs Placebo with Best Supportive Therapy Allowed in Both Arms in Patients with Myelofibrosis Who Have Been Previously Treated with One or More Janus Kinase Inhibitors

2014-0415 (clinicaltrials.gov NCT No: NCT02226172)

Principal Investigator: Srdan Verstovsek

Study Design: The goal of part one of this study is to learn if PF-0444913 is safe and tolerated when given to patients with myelofibrosis who were previously treated with a JAK inhibitor. The goal of the second part is to compare the effectiveness of PF-0444913 to placebo. PF-0444913 is an oral inhibitor of the Sonic Hedgehog pathway. Patients in part one will receive PF-0444913 orally once daily and patients in part two will be randomized to receive either PF-0444913 or placebo orally once daily. Study visits will be weekly during the first month and monthly thereafter.

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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 MF and anemia. 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. Study visits will be once per week for at least 4 months. This study is accepting patients with myelofibrosis and significant anemia.

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Phase 2 Open-Label, Dose-Escalation Study of NS-018, a JAK2 Inhibitor, in Patients with Myelofibrosis Previously Treated with Ruxolitinib

2011-0090 (clinicaltrials.gov NCT No: NCT01423851)

Principal Investigator: Srdan Verstovsek

Study Description: The goal of this clinical research study is to find the highest tolerable dose of NS-018 that can be given to patients with MF. The safety and efficacy of this drug will also be studied. NS-018 is a drug that blocks the JAK2 protein, similar to ruxolitinib. Patients will receive NS-018 orally once daily. Study visits will weekly the first month, monthly for months 2-4, and then every 3 months thereafter. Only patients previously treated with a JAK2 inhibitor are eligible to enroll.

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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 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 weekly during the first month and then monthly thereafter.

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Phase 2 Study of Ruxolitinib and 5-Azacytidine (hypomethylating agent) in Patients with Myelodysplastic Syndrome/Myeloproliferative Neoplasm or Myelofibrosis

2012-0737 (clinicaltrials.gov NCT No: NCT01787487)

Principal Investigator: Naval Daver

Study Description: This goal of this study is to learn if the combination of ruxolitinib and azacytidine can help to control disease in patients with myelodysplastic syndrome (MDS)/MPN or myelofibrosis. The combination of ruxolitinib and azacytidine may improve the overall effectiveness of each drug. Ruxolitinib will be taken orally twice per day for the first 3 months, after which time low-dose azacytidine will be added. Azacytidine will be given intravenously daily for the first 5 days of each 28-day cycle.

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Phase 2 Study of Brentuximab Vedotin (SGN-35) in Patients with CD30-Positive Aggressive Systemic Mastocytosis with or without an Associated Hematological Clonal Non-Mast Cell Lineage Disease

2012-0734 (clinicaltrials.gov NCT No: NCT01807598)

Principal Investigator: Srdan Verstovsek

Study Description: The purpose of this study is to determine if the drug brentuximab vedotin (Adcetris) can help control systemic mastocytosis. Brentuximab

vedotin is a biological therapeutic designed to bind to a certain protein (CD30) on cancer cells and kill them. Patients will receive brentuximab vedotin intravenously once every 21 days for up to 8 cycles. Study visits will be weekly during the first month and then twice a month thereafter.

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Prospective Evaluation of Ruxolitinib Efficacy 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. Patients will receive ruxolitinib orally twice daily for 24 months.

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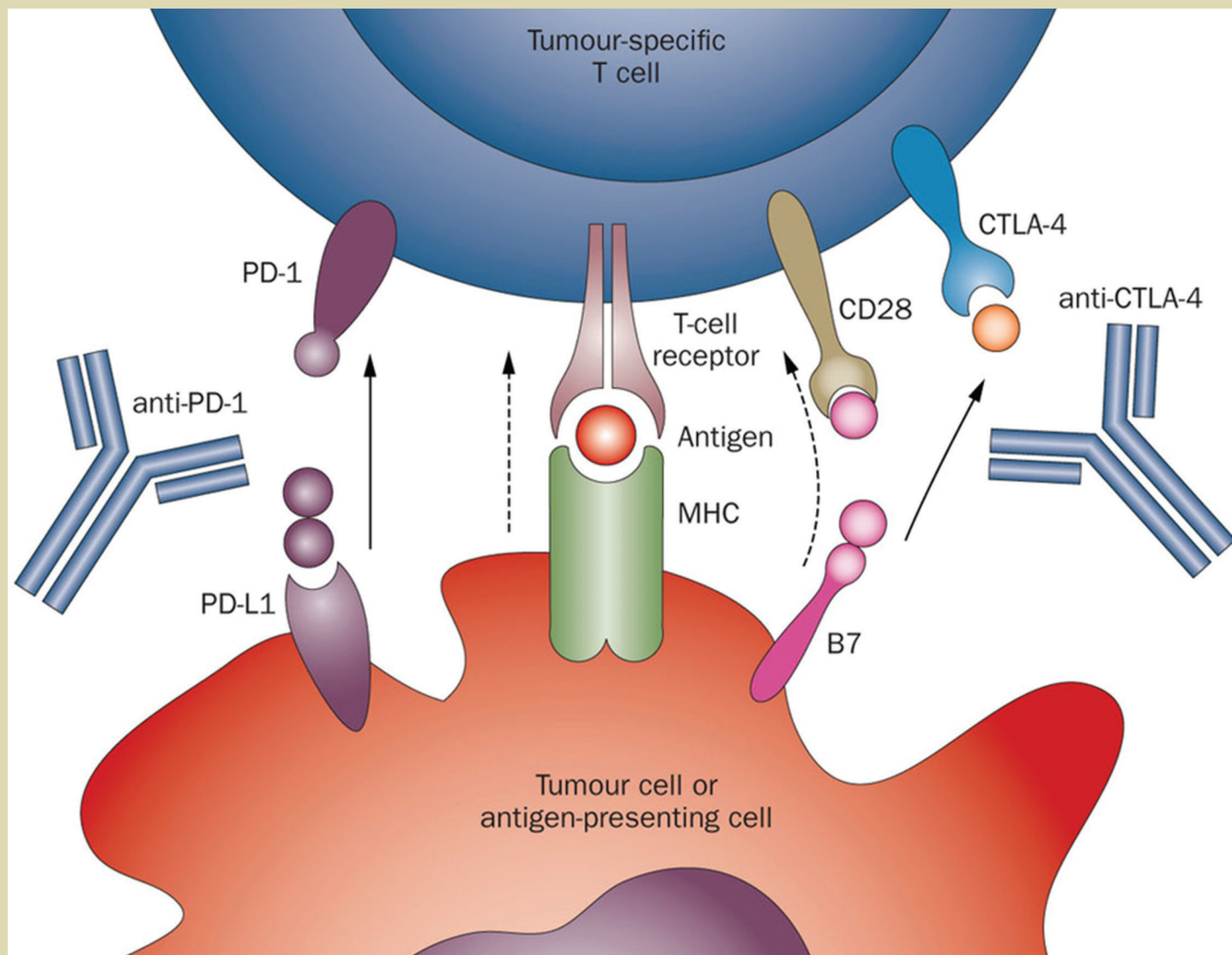
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Immunotherapy for Myelofibrosis

By Kate Newberry
and Srdan Verstovsek



T-cells (shown in blue) have molecules on their surface (T-cell receptor) that can recognize antigens, which can be tumor cells or another antigen-presenting cell (e.g., bacteria). Binding of the antigen to the T-cell receptor sends a wake-up signal to the T-cells, telling them to start multiplying and killing the foreign invaders. However, there are other molecules on the surface of T-cells that can send a signal that turns the T-cells off (e.g., PD-1 or CTLA-4). When the T-cell encounters an antigen-presenting cell (such as a tumor cell) that has PD-L1 on its surface (or another molecule called B7), the PD-1 receptor (or CTLA-4) on the T-cell binds to the PD-L1 receptor (or B7) on the tumor cell, sending a signal that turns off the T-cells. The checkpoint inhibitors, such as anti-PD-1 (nivolumab) or anti-CTLA-4 (ipilimumab), bind to the receptor on the T-cell (PD-1 or CTLA-4), which prevents the tumor cell with PD-L1 (or B7) from binding and turning off the T-cells.

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Immune checkpoint inhibitors are the latest weapons in the war on cancer. This type of immunotherapy represents a dramatically different strategy for fighting cancer. Instead of targeting the tumor cell directly, immune checkpoint inhibitors act by harnessing the body's immune system to fight the cancerous cells. Most importantly, because they activate the body's own immune system, these new therapies have the potential to work in many different types of cancer. Immune checkpoint inhibitors are already approved for use in metastatic melanoma (ipilimumab, pembrolizumab, and nivolumab) and non-small cell lung cancer (nivolumab) by the US Food and Drug Administration. In fact, some patients with metastatic melanoma who were the first to be treated with checkpoint inhibitors have now been in remission for more than a decade.

What are immune checkpoints and how can we harness our immune system to fight cancer?

First, we need to understand how the immune system works. The immune system is a network of white blood cells, tissues and organs that protect the body from infections. White blood cells are produced in the bone marrow, spleen and thymus and they circulate throughout the body looking for foreign invaders. There are several types of white blood cells that each have a specific role in maintaining the immune system. One type of white blood cell, called T-cells—the so-called “soldiers of the immune system” destroy the foreign invaders. These foreign invaders are called antigens, which tell the immune system to create antibodies to fight the foreign invader. Bacteria, viruses or allergens (such as dust or pollen) are common types of antigens, but cancer cells can also be recognized as antigens. T-cells are constantly surveying the situation in your body, on the lookout for foreign invaders. When the T-cells recognize an antigen, they are activated and begin replicating themselves, creating

an army of cells that will recognize and kill the “foreign invader” (e.g., bacteria, viruses, or tumor cells). However, the immune system is complex and it has multiple checkpoints that act as “brakes” to prevent the destruction of the body's healthy cells. In recent years, scientists have found that tumor cells often take advantage of these checkpoints to escape detection by the immune system. One of these checkpoints is PD-1 (programmed death-1), a protein (receptor) found on the surface of activated T-cells. Binding of a protein called PD-L1 to the PD-1 receptor tells the soldiers (i.e., T-cells) to stop fighting. PD-L1 is often expressed on the surface of cancer cells where it acts as a signal to stop the T-cells' attack, allowing the cancer cells to evade detection and destruction by the immune system. Checkpoint inhibitors are proteins that bind to receptors such as PD-1 on T-cells, preventing the binding of PD-L1, which “releases the brakes” on the immune response (see Figure). The T-cells are then

able to more effectively recognize and kill the tumor cells.

One checkpoint inhibitor that binds to PD-1 is called nivolumab (Bristol-Myers Squibb). Nivolumab is already approved by the FDA to treat advanced melanoma and lung cancer, and early-phase studies of nivolumab in some types of lymphoma have shown promising results, suggesting that modulation of the immune response may be a promising strategy for treatment in blood cancers as well as solid tumors. A phase 2 study of nivolumab in patients with myelofibrosis is now open and enrolling patients at The University of Texas MD Anderson Cancer Center, with Dr. Srdan Verstovsek, MD, PhD as Principal Investigator. The goal of this study is to determine the efficacy and safety of nivolumab in patients with myelofibrosis. Nivolumab will be given intravenously every 2 weeks for 16 weeks followed by 1 dose every 12 weeks.

MPN Research: YOU Can Make a Difference

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.

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Resources for Patients

2015 Patient Education Symposia hosted by MPN Advocacy & Education International



- **September 2015** in San Diego, California – Women in MPN (date TBD)
- **October 29, 2015** in Seattle, Washington

For more information visit:
www.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** (MPN AEI) provides educational programs, materials, and resources for patients, caregivers, physicians, and entire healthcare teams to improve their understanding of MF, PV, and ET.

Other Online Resources:

MPNforum Monthly...the MPN community's hometown paper



MPNforum Monthly is a not for profit online magazine founded by MPN patient Zhenya Senyak. MPNforum monthly

(mpnforum.com) publishes stories, features and columns that impact the lives of patients suffering from an MPN.

MPDSUPPORT.ORG

Founded in 1994 by patient advocate, Robert Tollen, the **MPD-SUPPORT** website and email list has offered interesting information on MPNs. Anyone is welcome to subscribe and all archives are available. Robert, who was diagnosed with PV in 1990 has also created a closed Facebook group with more than 1500 members. For more information or to join the list serve go to MPNSUPPORT.ORG or email listserv@listserv.icors.org with "subscribe mpdsupport" in the body of the email. To join the Facebook group go to:
<https://www.facebook.com/groups/375525335856981/>



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 (www.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 www.mpninfo.org.



American Partnership
for Eosinophilic Disorders

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 www.apfed.org.

The Mastocytosis Society

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.



www.tmsforacure.org.

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 led by Karen Stern meets quarterly.

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

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

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