Dear Ms. Vesely:

I am a hematologist, a tenured professor at the Mount Sinai School of Medicine, and have spent my 42 years in academics in the area of bleeding and clotting disorders. ITP has been, and continues to be, a common adult and pediatric illness that offers major challenges for those who do not achieve a remission. In addition to the constant threat of bleeding and fatigue, the complications of the many therapeutic interventions are not inconsequential.

The discovery that a thrombopoietin molecule can control platelet production, and its suboptimal function in many cases of ITP, has led to the first therapy for this disease, AMGEN 531, also known as NPLATE (romiplostim). This molecule is capable of increasing and maintaining platelet counts in a substantial majority of recipients without fear of any significant side effects.

All my patients have had a satisfactory response. Their lives have been markedly improved by allowing full activities, emotional security, and a confidence not known by most for many years.

This innovative and highly successful therapy deserves licensing so that those who could not be reached by the limitations of clinical trials could have this medication available.

Sincerely,

Louis M. Aledort, MD, MACP

LMA/nds

Louis M. Aledort, MD, MACP
The Mary Weinfeld Professor of Clinical Research in Hemophilia
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1006
New York, NY 10029-6574
Tel.: 212.241.7971
Fax: 212.987.3326
louis.aledort@mountsinai.org

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 7:53 PM
To: Vesely, Nicole
Subject: NPLATE (romiplostim)

Dear Nicole,
I am writing to tell you that I am a person with ITP who could really benefit from the approval of NPlate.

I have been diagnosed since October, 2005. My platelet count has remained stable at about 50,000 for about 1 1/2 years and this past November, it dropped down to 18,000 (while on 20mg. of prednisone). Two weeks ago I received IVIG treatments and am being weaned off prednisone once again.

I have been reading about NPlate and know that this drug would help so many people, including myself. ITP is a devastating disease for someone like me. I am a college professor who has always been in great health. I have always been active and now I tire easily and don't have the zest that I once had. I am still a very young 57 years old and want so desperately to find something that will get my platelets back to the normal level.

Please help us get our life back.
Sincerely,
[redacted]

Vesely, Nicole

From: Aldric [friargadding@yahoo.com]
Sent: Monday, February 18, 2008 5:06 PM
To: Vesely, Nicole
Cc: John.Bachman@bhsnet.org
Subject: FDA & AMG531

Dear Ms. Vesely,

My nurse friend, [redacted] R.N., sent me today a note about a meeting to discuss AMG531
at an FDA meeting for which you are the contact person.

I want to believe that this note to you is adequate enough so that my small voice will be heard at that meeting.

For you see, I cannot praise this experimental drug highly enough! I am under the conviction
that it has saved my life. For at least two years now, after many months of trying every conceivable cancer drug, my wonderful hematologist/oncologist, Dr. [redacted] M.D.,
has been treating my ITP with weekly injections of what will be called Nplate and/or romiplostim. In my view, the shots do the trick! My platelet counts are usually well within
the normal range, and truth to tell, when the count is less it pleases me just fine. For I am
made aware by TV ads about the 'sticky' nature of platelets and I let myself be concerned about strokes!

I would like to thank AMGEN and the two men mentioned here for all the 'compassionate' care
and consideration I have been given since my sister, [redacted]ann, a Registered Nurse, noticed a short write-up in Science News about the drug I am so glad we found.

If I keep lauding AMG531, AMGEN will want to make commercials with my talking head giving testimonials!

But let me just say that I hope at some time in the future I will be able to buy and use this
therapy on my own, and see doctors far less often!

At 71, there are still many years of longed-for travel in me!

Bon Voyage!

With all best wishes, yours,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 9:17 PM
To: Vesely, Nicole
Subject: ITP

Please do whatever is necessary to effect the approval of NPlate romniplostim (AMG531) or any other form of treatment of Idiopathic thrombocytopenia purpura (ITP).

This is a life altering, life threatening disease.

[redacted]

February 24, 2008

Nicole Vesely
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: BLA 125268, proposed trade name NPLATE (romiplostim), Amgen, Inc.

Dear Ms. Vesely:

My name is [redacted] I am and have been a patient of Dr [redacted] at the [redacted] since 2002 when I was diagnosed with immune thrombocytopenia purpura (ITP). My platelet counts were ranging between 10,000-30,000.

It was recommended that I have [redacted] After deciding that I did not want to have a [redacted] (I did not like the success rate of 60% and the fact that there is no effective method to predict a person's response to this surgery), I was started on corticosteroids. The corticosteroids did increase my platelets, but whenever they were tapered my platelets would fall.

In December 2003, after being on corticosteroids for over a year, I developed a [redacted] March 2004. In addition to this, I developed [redacted] and [redacted] All of these side effects were attributed to the corticosteroid use.

I started to worry about hurting myself when doing regular activities that I had done in the past, i.e., riding my bike, jogging, traveling long distances by car, cutting up vegetables and fruit, etc. I did not want to get into an accident and run the risk of being unable to stop bleeding.

In 2006, I was invited to participate in the study **"An open label study evaluating the safety and efficacy of long-term dosing of AMG531 in thrombocytopenic subjects with immune (Idiopathic) thrombocytopenia purpura (ITP)". Amgen protocol # 20030213.** I was happy to take part in this study as it was another option for the treatment of ITP.

February 11, 2008

Nicole Vesely
Center for Drug Evaluation and Research Food and Drug Administration
5630 Fishers Lane Room 1093
Rockville, MD 20857

Dear Nicole Vesely,
I am writing this to express my interest in the hearings to be held on March 12th & 13th regarding NPlate (romniplostim – AMG531).
I have ITP and tried many treatments, to date nothing has worked. I would like to have a normal life without waking every day with nose bleeds which are constant through out the day. My counts are below 10,000, what more can I say. I have to be mindful daily to be careful and at this point even a dental visit is a major concern. Were in I can not get treatment needed since the counts must be at least 30,000.
My hope is for a treatment, so that I may have a normal day, with no bleeding, bruising and more energy.
Please state my concerns for the approval of this new treatment at the hearings. I know I am not alone in this life altering disease.

Best Regards,

[redacted]

Vesely, Nicole

From: C.Corlan [corlan@speakeasy.net]
Sent: Wednesday, February 27, 2008 3:38 PM
To: Vesely, Nicole
Subject: AMG 531's effect on my life

To Whom it May Concern,

I have been on AMG 531 for several months as a treatment for ITP. Prior to starting on AMG 531 I had platelet levels which were both chronically low (consistently running less than 80) and subject to unexplained sudden falls - they would suddenly begin to drop by 15 or 20 counts per week, and would continue until my Doctor intervened, generally about the time they hit the low 20's. [redacted] limited success in my case - the platelets would rise, plateau, and then fall again, generally stabilizing in the 60 - 80 range for a bit, then unexpectedly dropping back down to dangerous levels.

I was dependent on weekly or semi-weekly visits to my Hematologist's office to track my platelet counts; there was the constant concern that the platelets would drop to levels requiring hospitalization if left unmonitored for longer than a couple of weeks. This posed a substantial stress; I could not make it to work before 10 AM on days when I went to the Hematologist's, and I was deeply grateful that I have excellent health insurance and could therefore afford the frequent visits and the occasional (very expensive!) [redacted] treatments. I could never wear shorts or sleeveless tops because I always had too many bruises - any brush against something, often too light a contact for me to remember, would result in a bruise.

I also could not take a simple aspirin for pain - NSAIDs (aspirin, advil, alleve, etc.) reduce the effectiveness of platelets and if one's platelet count is already low NSAIDs can cause dangerous internal bleeding. Tylenol is permitted, but it has no effect on me - it does not relieve my pain. I am prone to [redacted] and to [redacted] so there were a number of occasions when I had to miss work from pain which could have been handled by 2 Advil Migraine or 2 aspirin.

When I began the AMG 531 treatments my platelet count immediately went into the normal range and has stayed there. I am able to see my Hematologist once a month for monitoring, instead of once a week. I have better energy reserves, whether from the reduction in stress or from just being healthier is hard to tell. I have missed much less work, both because I don't have as many appointments and because I can once again take aspirin and advil when I need them. I have also started exercising again; I have less concern about bruising from the exercises and I am able to take aspirin to combat the post-workout muscle aches. This increases my overall health and well-being immensely.

In short, AMG 531 has greatly improved my quality of life.

[redacted]

[redacted]

2/27/2008

I have just completed my 93rd week on this study, and I am happy to say that my platelets are now in an acceptable range. My experience with this drug has been outstanding. I was given very detailed instructions on how to self-inject the AMG 531 via continuing patient education through a nurse and a video tape that Amgen provided. Also included with my startup material was a placemat with step-by-step instructions on how to prepare the drug for injection which I find very helpful every time I inject.

In addition, the only minor side effects I have experienced were an occasional slight headache and nausea which I am happy to report have not occurred for the past two-three months.

I would have to say that my quality of life has improved substantially since starting AMG 531. I no longer have to worry about the side effects of corticosteroids and my [redacted] can remain intact. But best of all I now have the freedom to resume my active life as it was before I was diagnosed with ITP.

Thank you for giving me the opportunity to relate my experience with AMG 531. Please let me know if you need any further information.

Sincerely,

[redacted]

Email: [redacted]
Phone: [redacted]
Fax: [redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 6:57 PM
To: Vesely, Nicole
Subject: From ITP Patient receiving AMG531/NPlate

Nicole:

I wanted to briefly share with you the impact AMG531 has had on my quality of life.

It is my understanding there will be a meeting on March 12, 2008 in Maryland.
I read that the FDA is hosting a public meeting on
NPlate, also known as romniplostim or AMG 531, the
first of these new treatments to be considered for
approval. Since this is the first time the FDA is reviewing
a TPO agent, I heard they are seeking public comments as part
of their regular approval process.

I have been struggling with ITP for 22 years. I had to have [redacted] when I was only 27 yrs. old.

The trials and tumultuous life I have lived since then is much too lengthy for an e-mail.

I truly never thought I would see a way to treat ITP in my lifetime.
Thanks to Dr. [redacted] persistence and expert knowledge,
I am now able to enjoy participating in aspects of life I never thought would be in the foreseeable future.

During the trial, I was unfortunately on the placebo for 26 straight weeks.
I live in [redacted] so the drive to [redacted] every week was stressful at best.
Looking back, I am not sure how I was able to participate weekly especially when I was not feeling well due to my condition.

There were days when I felt like I was riding a psychotic horse into a burning stable.

There were also many times I wanted to drop out of the program, however, friends, family, and Dr. [redacted] encouraged me every step of the way.

Once the trial was completed and I learned that I was on the placebo, I was then eligible for the drug.

I have been fortunate enough to only make the trip to [redacted] monthly.
My counts are within the guidelines to allow me to do so.
Between that and feeling so much better overall, I am sincerely grateful to all those involved with making this drug a possibility of hope for me and others who have been dealt this grievous card.

Since I have totally missed *healthy adulthood* -
I look forward to enjoying my 50's and hopefully many more years ahead.

I would be very appreciative if you could pass my note on to those involved with the approval of AMG531/NPlate through the FDA.

"I met a man once who did a lot of mountain climbing.
I asked him which is harder, ascending or descending ?
He said, without a doubt, descending because in ascending, you are so focused on reaching the top- you avoid mistakes.

The backside of a mountain is a fight against human nature . . . . . .
You have to care as much about yourself on the way down as you did on the way up ~ "

*** Mitch Albom ***

Thank you, in advance, for your time and consideration on my behalf.

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 7:53 PM
To: Vesely, Nicole
Subject: support AMG531

Dear Nicole,

I called the Platelet Disorder Support Association in the spring of 2006, very concerned for my sister, [redacted] who had been hospitalized and diagnosed with ITP in December 2005. She is an adult with chronic immune (idiopathic) thrombocytopenia purpura who is [redacted] and had had an inadequate/intolerant response to corticosteroids and immunoglobulins. As a result of this phone call we contacted [redacted] He got my sister into the research pool to use AMG531, in June, 2006. In July, 2006, her platelets were stable (at 75) for the first time in seven months. She has continued receiving weekly injections of AMG 531 and her platelets have been as high as 200. This drug has given my sister her life back with minimal side effects. I would strongly recommend this treatment to anyone suffering the fear and instability of ITP. My sister fought a desperate battle to find an effective treatment for her ITP. AMG531 has been the one and only answer for her.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Monday, February 11, 2008 10:41 AM
To: Vesely, Nicole
Subject: RE: NEW DRUGS-TREAMENTS FOR "ITP" ASAP
Follow Up Flag: Follow up
Flag Status: Red

YES VERY MUCH. I HAVE HAD A LONG LEARNING CURVE CONCERNING ITP, I BELIEVE THAT MY SON CASE IS MULTIPLE FACTORS..... 1) EXPOSURE TO HEAVY METALS LEADING TO ANEMIAS. 2) THE STAGE OF BONE GROWTH 3) EXPOSURE TO BACTERIA & VIRUS INFECTION..... HE DELIVERED MEDICAL SUPPLIES TO INVALIDS AND BECAME ILL. 4) HE HAD H-PYLORI BACTERIA THAT IS RELATED TO STOMACH ULCERS. 5) ACUTE STREPTOCOCCUS INFECTIONS ALL AT THE SAME TIME .
6) SEVERE WEIGHT LOSS OVER MANY MONTHS W/O KNOWING WHAT THE CAUSE WAS. 7) TREATMENT HAS BEEN IVG W/ STEROIDS 180 MGS /DAILY FOR MONTHS AND RITUXAN , HIS PLATELETS ARE UP AND DOWN, HIS BIGGEST COMPLAINT IS MORING NAUSEA W/ VOMITTING. WE HAVE REACHED OUT TO SUPPORT GROUPS AND TALKED W/ SPECIALISTS TO NOT OVER LOOK ANY TREATMENT. ALSO A BIG FACTOR IS WE HAVE [redacted] MY SON IS ON [redacted] AND WE HAVE APPLIED FOR [redacted] TO [redacted] THANK YOU. SINCERELY,

"Vesely, Nicole" <Nicole.Vesely@fda.hhs.gov> wrote:

[redacted]

Would you like this to be considered a Written Submission for the March 12th romiplostim ODAC meeting?

Thank You,
Nicole Vesely, Pharm.D.
LT, United States Public Health Service
Advisors and Consultants Staff HFD-21
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane (Bldg 5630)
Rockville, MD 20857
Phone: (301) 827-6793
Fax: (301) 827-6776
Email: nicole.vesely@fda.hhs.gov

From: [redacted]
Sent: Friday, February 08, 2008 6:00 PM
To: Vesely, Nicole
Subject: NEW DRUGS-TREAMENTS FOR "ITP" ASAP

Vesely, Nicole

From: [redacted]
Sent: Friday, February 08, 2008 6:00 PM
To: Vesely, Nicole
Subject: NEW DRUGS-TREAMENTS FOR "ITP" ASAP
Follow Up Flag: Follow up
Flag Status: Red

DEAR NICOLE : I WOULD LIKE TO STATE THAT I HAVE A SON W/ ITP AND HAVE BEEN THROUGH QUITE A LOT, UPS AND DOWNS; ANY NEW TREATMENTS WOULD BE A GOD SEND, THERE IS VERY LITTLE CHOICE IN TREATMENTS AND NOT EVERYONE RESPONDS THE SAME . I DESIRE TO SEE NEW METHODS AND DRUGS BE AVAILABLE ASAP . THANK YOU. SINCERELY, [redacted]

Vesely, Nicole

From: [redacted]
Sent: Saturday, February 09, 2008 11:54 AM
To: Vesely, Nicole
Subject: March 12th FDA Meeting - AMG 531
Follow Up Flag: Follow up
Flag Status: Red

Dear Nicole Vesely,

I have been informed of the FDA's upcoming meeting to discuss the approval of a new treatment for ITP patients, called NPlate, also known as romniplostim or AMG 531. I think this is a wonderful step, as there are not many treatments on the market, and there is no known "cure" for Chronic ITP patients. My family and I have been dealing with ITP for almost 1-1/2 years, with no end in sight. The more research done and the more treatments that are approved and available to the public is a huge measure of hope to any family suffering with a diagnosis of ITP (Ideopathic Thrombocytopenic Purpura). This disease can be extremely frustrating to live with, especially if the person was active before the diagnosis. The patient is very limited in activities they can engage in, due to severe risk of injury and internal bleeding. I am very encouraged to hear researchers are still trying to figure out ways to make the bone marrow start making new platelets! Please consider this email as a petition to have NPlate approved. Thank you for your time.

Warmest Regards,
[redacted]

[redacted]

[redacted] February 12. 2008

Nicole Vesely
Center For Drug Evaluation and Research HFD-21
Food and Drug Administration
5600 Fisher Lane
Rockville, MD 20857

Re: AMGEN 531, Protocol # 20030213

FDA Meeting 3/12/08 and 3/13/08

My name is [redacted] and I am a patient of [redacted]

I am an ITP patient since more than 12 years. I have been treated by doctors in the USA, Germany and Hong Kong. None of the treatments and medications prescribed, including [redacted] helped to raise my platelet count to acceptable levels. Immunoglobulin was often the only temporary help left

Since taking the NPLATE medication my platelet count has risen to average well above 100 and this by getting the smallest prescribed dose of 1 mg.I experience no side effects from taking NPLATE.

It is my sincere wish that NPLATE will be approved and made available for use in ITP.

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Friday, February 15, 2008 10:31 PM
To: [redacted]
Subject: Re: Your input wanted for an important FDA meeting

Ref. to FDA meeting March 12, 13, 2008 and AMG531 approval:

I have had ITP(platelets keep getting destroy by my body or not enough platelets are produced by my body) since about year 2001.
I was given steroids for a while, then other treatments, all of which did not work. Finally, I am receiving [redacted] treatments. I do expirience some[redacted]

We need AMG531 in order to live a more normal life. Low platelets deminishes my quality of life. [redacted] that requires effort I don't want to do. We need help.

Please help in supporting the approval of AMG531/NPlate.

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 9:26 PM
To: Vesely, Nicole
Subject: AMG 531

To whom it may concern,

Our daughter has coped with chronic ITP for 10 years now. She is eleven years old and we have been through the rollercoaster of this disease. Like many, we are in desperate need of anything that will raise her platelet level so that she is in a safe zone. We have exhausted all possible means of treatments and medications, while her count continues to plunge below 20,000.
We urge and beg you to approve this type of drug. You will affect peoples' lives in ways that they have never thought possible. Again please approve and let's get this process going as quickly as possible for the sake of so many in need.
Counting on all of you,
[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 11:54 PM
To: Vesely, Nicole
Subject: Amg531...FDA approval

Dear Nicole,

The letter below was written on my behalf by my sister [redacted] She is correct in most of her facts, however, my platelets did not stablize at 75 within just a month, it took several months. I kept a journal in the early months so if you need further information please call me.

Side effects, in the big picture, were moderate to minimal at times. Side effects in early months mainly. Now side effects such as aches, pains, headaches, myalgia, are primarily within the first 48 hrs of injection.

Amg531 was truly a "miracle" for me. My physicians tried numerous treatments adn I responded to NONE. I was diagnosed with Severe Refractory ITP, when my sister read information abou[redacted]MD, and I was blessed to be admitted to the research program for AMG531, taking my first injection on June, 6 2006.

Please contact me if you need furhter information or assistance from me.

[redacted]

-----Original Message-----
From: [redacted]
Sent: Wednesday, February 27, 2008 6:53 PM
To:
Subject: support AMG531

Dear Nicole,

I called the Platelet Disorder Support Association in the spring of 2006, very concerned for my sister, [redacted] who had been hospitalized and diagnosed with ITP in December 2005. She is an adult with chronic immune (idiopathic) thrombocytopenia purpura who is [redacted] and had had an inadequate/intolerant response to corticosteroids and immunoglobulins. As a result

of this phone call we contacted Dr. [redacted]. He got my sister into the research pool to use AMG531, in June, 2006. In July, 2006, her platelets were stable (at 75) for the first time in seven months. She has continued receiving weekly injections of AMG 531 and her platelets have been as high as 200. This drug has given my sister her life back with minimal side effects. I would strongly recommend this treatment to anyone suffering the fear and instability of ITP. My sister fought a desperate battle to find an effective treatment for her ITP. AMG531 has been the one and only answer for her.

Sincerely,

[redacted]

[redacted]

Comments to the FDA Oncologic Drugs Advisory Committee Regarding NPlate (AMG531) for Consideration at their Meeting of March 12-13, 2008

My name is [redacted] and I have Immune Thrombocytopenic Purpura ("ITP"). I submit these comments for the Committee's consideration with the hope that it will approve AMG531 at the earliest possible date.

I was in the Phase 3 (randomized double-blind placebo-controlled) and Phase 4 (open label) clinical trials of AMG531 from July 2005 through October 2006 (with a brief break between phases) for non-splenectomized refractory patients. [redacted] My experience with AMG531 was positive. I suffered very few and very minor side effects (specifically, post-injection stuffy/runny nose), which resolved within hours of my weekly injection, and which disappeared completely after a few months on the drug. Although I was ultimately released from the study because I was not able to achieve a stable platelet count above 30,000, AMG531 did keep my platelet count higher than normal for me. (My average platelet count while on AMG531 was 43.97; average off AMG531 was 34.62. I have attached an Excel document which contains three sheets. The first sheet shows all of my platelet counts since I was diagnosed in December 2004. The first highlighted area (purple) shows my platelet counts on placebo (Phase 3); the second highlighted area (light blue) shows my platelet counts on AMG531. The other sheets show comparisons of my counts with and without AMG531.)

I urge the Committee to recommend approval of AMG531 (NPlate). For many people with platelet disorders or those experiencing low platelet counts due to chemotherapy or other disease, AMG531 can be an enormous help with almost no side effects. There are very few drugs on the market today that can make that claim. Low platelets can cause a whole spectrum of symptoms, including extreme fatigue, body aches, headaches, nose bleeds, bruising and insomnia.

ITP is such an odd disease. It is unpredictable and can have a profound effect on the quality of life of those suffering from it. At this point, there is no cure for ITP, and the few treatments available often have severe side effects. AMG531 is like a miracle.

I have never commented on a drug before. I do so today because, while AMG531 has been described as an "orphan drug," ITP is an orphan disease. The segment of the population suffering from ITP is relatively small. AMG531 can help not only those of us in this minority, but a larger group of patients as well: patients receiving chemotherapy, those with liver disease, HIV, and other serious health issues. I urge the Committee to recommend approval of AMG531 (NPlate). Thank you for your time.

[redacted]

12/22/2004	25	
12/23/2004	29	
12/28/2004	81	
1/4/2005	37	
1/12/2005	44	
1/13/2005	62	
1/20/2005	61	
1/24/2005	79	
1/27/2005	67	
2/3/2005	34	
2/10/2005	32	
2/11/2005	30	
2/11/2005	31	
2/12/2005	57	
2/18/2005	125	
2/22/2005	70	
2/24/2005	62	
3/3/2005	53	
3/10/2005	86	
3/18/2005	66	
4/7/2005	36	
4/7/2005	39	
4/26/2005	67	
5/5/2005	45	
5/12/2005	42	
5/19/2005	46	
6/6/2005	24	
6/7/2005	28	
6/9/2005	35	
6/16/2005	19	
6/30/2005	41	
7/7/2005	26	Enter Phase 3 study (placebo)
7/13/2005	33	
7/19/2005	21	
7/21/2005	23	
7/27/2005	26	
7/29/2005	21	
8/3/2005	23	
8/10/2005	15	
8/12/2005	22	
8/15/2005	18	
8/18/2005	28	
8/24/2005	26	
9/1/2005	17	
9/7/2005	38	
9/14/2005	20	
9/21/2005	11	
9/23/2005	15	
9/27/2005	16	
9/28/2005	39	[redacted]
10/5/2005	18	
10/13/2005	14	
10/19/2005	13	
10/27/2005	38	[redacted]
11/2/2005	15	

11/10/2005	19	
11/16/2005	19	
11/23/2005	9	
11/30/2005	16	
12/7/2005	47	
12/14/2005	19	
12/21/2005	20	
12/23/2005	22	
12/28/2005	20	
12/30/2005	16	
1/3/2006	17	End of study
2/2/2006	25	
2/15/2006	16	Enter Phase 4 study — first injection of actual drug
2/20/2006	40	
2/22/2006	33	
3/1/2006	23	
3/9/2006	26	
3/15/2006	32	
3/22/2006	56	
3/29/2006	111	
4/6/2006	23	
4/12/2006	17	
4/19/2006	72	
4/26/2006	21	
5/4/2006	39	
5/10/2006	113	
5/17/2006	83	
5/24/2006	18	
5/31/2006	28	
6/7/2006	89	
6/13/2006	58	
6/20/2006	51	
6/21/2006	28	
6/28/2006	21	
7/5/2006	47	
7/12/2006	66	
7/19/2006	56	
7/27/2006	26	
8/2/2006	32	
8/9/2006	41	
8/16/2006	78	
8/24/2006	53	
8/30/2006	14	
9/7/2006	17	
9/13/2006	35	
9/21/2006	39	
9/27/2006	18	
10/4/2006	35	
10/11/2006	35	
10/19/2006	18	
10/24/2006	14	Taper begins ([redacted]
10/25/2006	48	
11/1/2006	20	Release from study
11/9/2006	9	
11/10/2006	7	
11/11/2006	8	
11/13/2006	9	

11/30/2006	9
12/14/2006	18
12/22/2006	9
1/23/2007	25
2/22/2007	25
3/23/2007	12
5/15/2007	26
6/7/2007	17
7/10/2007	22
8/9/2007	37
9/14/2007	20
9/17/2007	21
9/20/2007	18
9/23/2007	68
9/26/2007	79
10/2/2007	49
10/22/2007	29
10/25/2007	38
2/6/2008	27

elet nts 3531		Platelet Counts w/out AMG531		Platelet Counts since last dose increase		Average Count with AMG531	Average Count w/out AMG531
0/2006	40	12/22/2004	25	7/12/2006	66	43.97	34.62
2/2006	33	12/23/2004	29	7/19/2006	56		
1/2006	23	12/28/2004	81	7/27/2006	26		
9/2006	26	1/4/2005	37	8/2/2006	32		
5/2006	32	1/12/2005	44	8/9/2006	41		
2/2006	56	1/13/2005	62	8/16/2006	78		
9/2006	111	1/20/2005	61	8/24/2006	53		
3/2006	23	1/24/2005	79	8/30/2006	14		
2/2006	17	1/27/2005	67	9/7/2006	17		
9/2006	72	2/3/2005	34	9/13/2006	35		
3/2006	21	2/10/2005	32	9/21/2006	39		
4/2006	39	2/11/2005	30	9/27/2006	18		
0/2006	113	2/11/2005	31	10/4/2006	35		
7/2006	83	2/12/2005	57	Average:	39.23		
4/2006	18	2/18/2005	125				
1/2006	28	2/22/2005	70				
7/2006	89	2/24/2005	62				
3/2006	58	3/3/2005	53				
0/2006	51	3/10/2005	86				
1/2006	28	3/18/2005	66				
3/2006	21	4/7/2005	36				
5/2006	47	4/7/2005	39				
2/2006	66	4/26/2005	67				
9/2006	56	5/5/2005	45				
7/2006	26	5/12/2005	42				
2/2006	32	5/19/2005	46				
9/2006	41	6/6/2005	24				
5/2006	78	6/7/2005	28				
4/2006	53	6/9/2005	35				
0/2006	14	6/16/2005	19				
7/2006	17	6/30/2005	41				
3/2006	35	7/7/2005	26				

1/2006	39	7/13/2005	33
7/2006	18	7/19/2005	21
1/2006	35	7/21/2005	23
rage:	43.97	7/27/2005	26
		7/29/2005	21
		8/3/2005	23
		8/10/2005	15
		8/12/2005	22
		8/15/2005	18
		8/18/2005	28
		8/24/2005	26
		9/1/2005	17
		9/7/2005	38
		9/14/2005	20
		9/21/2005	11
		9/23/2005	15
		9/27/2005	16
		9/28/2005	39
		10/5/2005	18
		10/13/2005	14
		10/19/2005	13
		10/27/2005	38
		11/2/2005	15
		11/10/2005	19
		11/16/2005	19
		11/23/2005	9
		11/30/2005	16
		12/7/2005	47
		12/14/2005	19
		12/21/2005	20
		12/23/2005	22
		12/28/2005	20
		12/30/2005	16
		1/3/2006	17
		2/2/2006	25
		2/15/2006	16
		Average:	34.62

Platelet Counts w/AMG531
14
17
17
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February 20, 2008

To Whom It May Concern:

My name is [redacted] I am 28 years old, and have been living with ITP since August 2003. I have tried many drug therapies including Prednisone, Decadron, Solumedrol, [redacted] Vincristine, Cyclosporine, Danazol, and [redacted] I have also had [redacted] The [redacted] resulted in a raised platelet count for only 10 days. The only drugs that I have listed that have made a positive impact on my platelet count were the Decadron and the [redacted] All of the drugs listed resulted in many side effects. These included weight gain, neuropathy, raised cholesterol, high blood pressure, hair loss, muscle aches and weakness, headaches, acne, and thinning skin. They also cause emotional and physical distress. To say that my quest to find a drug that works with few side effects has been long, hard, and challenging is somewhat of an understatement.

My doctor's office was selected to begin dispensing AMG531 in 2006. I was selected to take part in this study. Unfortunately, for the first 6 months, I was randomly selected to receive the Placebo. After enduring that 6 month period, AMGEN provided me with the real drug. The real drug had almost an immediate positive effect on my platelet count. It started to rise. After years of platelet counts that have been at zero on numerous occasions, you can imagine my relief. Finally, something that worked!

My doctors, nurses, and I are still trying to find a dose that works for me, but we are close. If it gets FDA approved, we can possibly stray outside of the protocol lines, and gather data for me, not for a company. Because I have been fortunate enough to receive this drug, the amount of time spent at the doctor's office and the amount of Decadron that I have to take have both decreased. I have also gone from receiving [redacted] 2-3 times per week, down to only having to have [redacted] This is a huge improvement, and it definitely helps with the amount of time I need to take off from my regular work schedule.

AMG531 requires my presence at the doctor's office once a week. I get a CBC, and then a subcutaneous shot. The shot burns like crazy, but just knowing that it will raise my counts, I am more than willing to take the pain. Over the years, the couple of drugs that used to work in raising my counts have become less effective. Apparently, I have become more tolerant to them. I don't know where I'd be at this point in my life without AMG531, and I'm not really sure what I'll do if this drug is not FDA approved. There are not many treatment options left that can/will potentially raise my count. The side effects of those drugs are grim, and the likelihood of a positive outcome is not realistic. I fear that AMG531 will not get approved. Without this drug, my fear of dying is great, and the reality of death is very present.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 20, 2008 4:18 PM
To: Vesely, Nicole
Cc: [redacted]
Subject: (no subject)

To Whom It May Concern:

I have been diagnosed with ITP for over 8 years. During which time, I have been treated with many procedures and drugs.

Prior to participation in Amgen studies, I was getting [redacted] monthly.

I participated in the Phase 1 study and have been in the open dosage study the last 128 weeks. It is the only drug that I have responded to for my ITP. There have been no complications and I have not had to have any kind of rescue drug.

Additionally, the convenience of self-injection has improved my quality of life over the all day [redacted] process.

It is my sincere hope that the FDA approves AMG 531/ NPlate for use in ITP.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]

Sent: Friday, February 15, 2008 4:18 PM

To: nicole.vesley@fda.hhs.gov

Subject: AMG 531

I have had ITP for 8 years. I was taking 20 to 60 MG of prednisone a day and [redacted] every two weeks a [redacted] just to keep my platelets above 20 and me alive. I was accepted in the AMG 531 study 2 years ago. My platelets have averaged about 80 to 100. I have not had to have [redacted] since I have been in the program. I give myself an injection of AMG 531 once a week and take 10 MG of predispose ever other day. It has made a Hough change in my personal health. I ask you to approve AMG 531 for all of us who suffer with ITP.

Your truly,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 10:00 PM
To: Vesely, Nicole
Subject: FDA approval

As a person with ITP, now in remission, I am anxious for the FDA to approve AMG531and any and all other medications to help those of us who suffer with ITP. Thank you,[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 05, 2008 8:51 PM
To: Vesely, Nicole
Subject: AMGEN 531 Drug

I have been on the experimental program for this drug for 3 years. I have had no side affects that I am aware of. It has been wonderful. My periods used to be like having a miscarriage every month because they were so heavy due to ITP. My periods also lasted 7 to 10 days. During this time I had a melanoma taken off my shin without receiving platelets or any other drug that a "normal" person would have to have. My platelets were running between 10,000 and 20,000 prior to the AMGEN 531 drug. Now they run 150,000 to 250,000. I always had bruises on the bottoms of my legs as well as other parts of my legs, my arms and other places. Sometimes the bruises were because I bumped myself but many times the cause was unknown. I always worried about bleeding to death if I had been in an accident. I also worried about emergency surgery. I don't worry about that at all now. I was diagnosed 20 years ago and I have been through vincristine chemo, cytoxin chemo, prednisone, another man made male steroid, and a few other experimental treatments. I had a terrible reaction to each of these. With the AMGEN 531 drug, I forget that I have health problems. I have had such an increase in the quality of my life and less stress from worrying about bleeding internally.

I hope that the FDA will consider approving this drug for other people like me. It has certainly been a "miracle" drug for me.

Thank you for your time and consideration of my experience with this drug.

Sincerely,

[redacted]

Background

In May 2007, our 21-year-old daughter developed massive and deep bruises practically overnight. Blood tests at our doctor's office revealed that her condition was considered life threatening and that she needed to be taken to the hospital emergency room immediately.

Her blood platelets, which had been a healthy 249,000 months earlier, had plummeted to 3,000. She was diagnosed with immune thrombocytopenia purpura (ITP). In addition to the obvious bruises, she also was covered with the more subtle petechia—even having it inside her mouth. The high doses of prednisone administered in the hospital barely pushed her platelets to 13,000. An infusion of [redacted] provided a modest boost to enable her to be discharged from the hospital. Within two weeks, the prednisone was still ineffective, the [redacted] effect had faded, and her platelets dropped again to 15,000. Going to college out of state and due to graduate in May 2008, our daughter instead transferred to a local [redacted] university—losing almost a year of credits. But we were hopeful that the specialists and resources in her native [redacted] would be better able to treat her ITP. After a couple months of failed treatments, [redacted] seemed imminent.

Our Experience with AMG 531

We discovered the new thrombopoietin (TPO) treatments on medical websites and studied the articles in the New England Journal of Medicine and other medical publications. She qualified for the AMG 531 clinical trial and has been taking the medication for six months. Within one week, her platelets jumped to 350,000 and sometimes higher. Twice her dosage has been decreased and her platelets are in the 240,000 range most of the time. All other blood work is normal. She is healthy, taking a full load of upper level college classes, and working a part-time job. Graduation is again in sight. Unlike the standard protocol for ITP, finally a treatment is available that addresses the low platelets and leaves lives intact.

As parents, it is frightening to enroll your child in a clinical trial. We have put our trust in a promising treatment and we trust that the FDA will continue to strictly follow the long-term effects of NPlate. With this trust, we would like to request approval of NPlate with the hope that others with ITP and those who have low platelets as a result of chemotherapy treatments can receive the same treatment that our daughter has come to rely on.

Thank you for your consideration.

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Thursday, February 28, 2008 11:03 AM
To: Vesely, Nicole
Cc: [redacted]
Subject: NPlate(AMG531).

Dear Ms. Vesely:

I am writing to you with respect to the upcoming FDA meeting with regard to the approval of NPlate(AMG531). I strongly urge the FDA to approve NPlate(AMG531) as soon as possible.

I am a 44 year old wife and mother of three that has struggled with ITP for 23 years. I have tried every medical and homeopathic resource available to ITP patients for treatment and have been unsuccessful with each. Over time my body no longer responds at all to treatments that worked slightly or temporally for me in the past, such as prednisone and [redacted] As a result I am left to live in fear with platelet counts under 10,000. In addition, my platelet count has been lowering over time and I am left with little energy.

My wish is to define myself as an active healthy women, but for years I have been unable to do the things I love like horseback ride and ski, due to potential fatal results. In the past few years my platelet count is even too low to get my teeth cleaned and my need to sleep makes it almost impossible for me to work, exercise or spend quality time with my family. Fear overcomes me as I have watched my body hemorrhage throughout the years. I have been informed that [redacted] is available to me and I would actually receive close to [redacted] a week not to work. This is not what I want from my life or from the Government. What I, and so many other ITP sufferers need, is new options for treatment that can help us live a healthy and productive life, while avoiding the terrible side effects of the current drugs that appear to work for some currently.

In November, after much prayers for a new treatment for ITP to become available, I became part of a clinical trial for AKR501, which is a similar drug to AMG531, in that it too is a new thrombopoietin (TPO)-like treatments that prompts the bone marrow to make more platelets. At last, I have responded successfully to a treatment. At last, I have a normal platelet count ranging from 150,000 - 250,000. At last, I have the energy to get up with my children in the morning. At last I can have dental work, walk my dog, ski, horseback ride and work with the energy and enthusiasm. One might say this new treatment has given my "Groove Back"!

The research has been done, the clinical trials have been successful, now I beg the FDA to approve NPlate so that myself and others are guaranteed another option of treatment and a chance to live a healthy, happy and successful life.

Sincerely,

[redacted]

[redacted]

February 27, 2008

Oncologic Drugs Advisory Committee
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear FDA Oncologic Drugs Advisory Committee Members:

I am an adult female who was diagnosed with chronic immune thrombocytopenia purpura in 2004 at age 54. My case is remarkable for its severity and stubborn resistance to traditional ITP therapies. As a participant in the NPLATE/ romiplostim (AMG 531) clinical trial, I believe it is important for you to be informed of the incredible difference this drug has made in my life.

After 16 months of treatment failures (including prednisone, decadron, [redacted] rituximab, vincristine, danazol, and colchizine), two trips to the [redacted] and countless CBCs with platelet levels consistently below 10,000, I met with [redacted] principal investigator, in May 2005 to be evaluated for participation in the AMG 531 study. On a daily dose of 60 mg of prednisone and with 6,000 platelets, I was sick and weakened by the debilitating effects of the long-term use of high levels of corticosteroids. I felt as if my body had been in a slow-motion chemical train wreck and, based on the cautionary comments of my local physicians, I knew that if I continued on such high levels of steroids, I would likely be in a wheelchair losing my eyesight in less than a year – and still have platelet levels in an unsafe range.

In July 2005 I began participation in the AMG 531 clinical trial on a "compassionate use" basis. Since that time, my platelet levels have usually been in a safe – and, very frequently, normal – range. I am pleased to report that I no longer take daily doses of prednisone and the severe adrenal insufficiency I suffered as a result of that therapy has gradually been reversed. Last April I traveled from my home in [redacted] to attend our [redacted] in [redacted] and danced (yes, danced!) with [redacted] That I could be there at all was indeed a miracle. Today, I look forward to many more of life's celebrations and perhaps someday I'll be on hand to welcome a [redacted]

[redacted]

Being a clinical trial participant has been a rewarding, but not easy, task. My case is a challenging one, and dose adjustments and additional therapies have been required from time to time and are likely to be necessary in the future. Since beginning the trial, my husband and I have made more than a hundred [redacted] roundtrips between our home [redacted] to [redacted] office in [redacted] Our travel expenses are not covered by insurance and my husband has spent an enormous amount of time away from his business in order to make my participation possible. Clearly, we both look forward to NPLATE being available closer to home so that [redacted] can coordinate my treatment with my local hematologist.

Many times I have thanked God for the medical miracle that NPLATE has been for me and for other clinical trial participants. I also give thanks on behalf of those who will benefit from it in the future – those who, hopefully, will never have to experience the debilitating and painful side-effects of the treatments I once faced as an ITP patient.

I am very grateful to the researchers and medical professionals who have dedicated themselves to making this medical breakthrough possible and to you for your time and consideration of this life-saving, life-changing drug.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 10:05 AM
To: Vesely, Nicole
Subject: FDA Advisory Meeting 3/12
Follow Up Flag: Follow up
Flag Status: Red

I am planning to attend this meeting and give a short talk about my battle with ITP. However, should anything happen that would prohibit me from travel, I am sending a statement.

FDA Advisory Board Statement

My name is [redacted] from [redacted] I am 61 years old and I have had ITP for over 4 years. No one can say for sure how this happened to me but my platelet count began to drop rapidly after having pneumonia.

My hematologist's first treatment was with large doses of Prednisone. My numbers climbed quickly with this drug but the side effects were ugly and dangerous. I suffered extreme sweating, high blood pressure, mood swings, and swelling. I didn't recognize myself in the mirror. I can easily say that I would never want to resort to that treatment again. I understand that some people have a positive result from this drug, but most other patients that I have spoken with agree that this therapy is terrible.

The next treatment was with [redacted] which did not raise my platelets enough, but reduced my hematocrit to very low levels. So much so that I had to receive other drugs to raise my red blood count. I was exhausted all the time. I was getting very depressed, I didn't know if we would find any solution.

The next drug was [redacted] That had some success but lasted only about two weeks. The infusion took so long that I had to invest an entire day for each treatment. At that time, my hematologist told me that there was shortage of that drug. He scheduled me for surgery, hoping that a [redacted] would solve the problem. At this point, I had to receive all sorts of inoculations because I would no longer have [redacted]

I did not have [redacted] I sought out second and third opinions. These doctors did not recommend this [redacted] because of the low percentage of success in people over 40 years old. I began treatment with a different doctor.

The next drug was Rituxan from which I got a pretty good result. I had treatment weekly for four weeks, then monthly, bimonthly then three months after that. As you know this required infusion therapy. Mine was given at the [redacted]. This left me exhausted and unable to carry on with my regular daily activities. I did maintain a decent platelet level for more than a year after my last treatment. In my case, Rituxan was not without side effects. Besides having to sit for so many hours for each treatment, I developed blood

clots in my legs for which I had to be hospitalized to have a filter put in so that the clots can't travel to major organs. I now take Coumadin. This balance can be a very slippery slope. Also, I must add that the cost of Rituxan is huge. Even with insurance, my co-payment was for thousands of dollars each year.

My life had changed drastically. I cannot travel as I used to. I am traveling to Washington by train to speak to you today. Flying has caused more clots in my legs and is dangerous with very low platelet levels. My life has never been the same since I was diagnosed with ITP.

I do hope that this board will recognize that more research has to be done to find new treatments for ITP. So few people are even aware of this disease. I certainly had never heard of it until it happened to me. Drug companies must be urged to move forward to develop these treatments so that so many of us can return to our normal lives. So that adults and afflicted children will be able to participate in all their normal activities without fear that any injury could end their lives.

Vesely, Nicole

From: [redacted]
Sent: Thursday, February 07, 2008 12:26 PM
To: Vesely, Nicole
Cc: [redacted]
Subject: AMG 531

[redacted]

Nicole,
I am an ITP patient of Dr. [redacted] I am the only one testing at the [redacted] site that has been referred to as a "failure". I don't feel that's entirely true. Even though we haven't seen the rise in platelet's that we had hoped the AMG 531 injections make it possible for me to hold down a full time job which is paramount for a [redacted] Before this drug was available I was having to have [redacted] infusions every 5-6 weeks at a cost of approximately [redacted] per treatment. It not only was a very expensive band aide but the doctor was worried that I would develope a resistance to it and it would no longer be effective if needed. I am concerned that when the drug is released to the public that I and others like me will not be able to afford to take it. I hope the FDA approves AMG 531 as it has been a wonderful help to so many that I know fighting this disease and I would recommend it to others just beginning the battle.

Thank you for your time.

Sincerely,
[redacted]
Adult ITP Patient since 2001

9 Feb 2008

TO: WHOM IT MAY CONCERN
SUBJ: ROMIPLOSTIM (AMG 531)

MY NAME IS [redacted] I AM CURRENTLY BEING TREATED AT [redacted] FOR SEVERE NATURE OF ITP.

I AM A 79 YEAR OLD RETIRED MARINE (1945-1962) AND HAVE MAINTAINED THE HABIT TAUGHT ME IN THE CORPS OF KEEPING MYSELF IN GOOD PHYSICAL CONDITION. QUIT SMOKING IN 1970 AND QUIT DRINKING IN 1992. -UNTIL- APRIL 2006 WHEN [redacted] ON AUG 21, 2006. AFTER [redacted]

FOLLOWING SURGERY AND RECOVERY I UNDERWENT 7 WEEKS OF [redacted] RIGHT SIDE OF HEAD AND NECK. SINCE THAT TREATMENT, MY QUALITY OF LIFE HAS DIMINISHED CONSIDERABLY. IE: [redacted] I WENT FROM 195# TO 135# FROM TIME OF SURGERY TO AUG 2007. QUALITY OF LIFE WENT TO POOR. I STARTED HAVING CHEST PAINS AND SHORTNESS OF BREATH IN JUNE 2007.

AS A RESULT OF CONSULT WITH A [redacted] AND A FOLLOW UP OF MANY TESTS WHICH REVEALED [redacted] AND NEEDED TO BE REMOVED ASAP. FURTHER BLOOD TESTS REVEALED MY PLATLET WAS TOO LOW (6K) TO PERMIT SURGERY.

I WAS DIAGNOSED AS ITP AND UNDERWENT MANY APPLICATIONS OF INFUSION/TRANSFUSION [redacted] PLATLET COUNT WAS BROUGHT UP TO AN ACCEPTABLE LEVEL AND SURGERY WAS PREFORMED [redacted] IN OCT 2007. POST OP BIOPSY CONFIRMED [redacted]

SINCE THAT TIME I HAVE UNDERGONE MANY APPLICATIONS OF [redacted] TO TRY TO MAINTAIN AN ACCEPTABLE LEVEL OF PLATLET COUNT THAT WOULD PROTECT ME FROM BLEEDING IN CASE OF A NEEDED SURGERY OR ACCIDENT. IT WAS FINALLY DECIDED TO APPLY [redacted] ON TWO CONSECUTIVE DAYS WITH A 9-10 DAY INTERVAL

THIS IS THE PROGRAM I AM CURRENTLY FOLLOWING.

I HAVE MANAGED TO GAIN 15# BUT APPETITE IS POOR. I AM FORCING MYSELF TO EAT, BALANCE IS POOR FROM ABOUT 5 DAYS AFTER TREATMENT AND ENERGY LEVEL DOES NOT EXIST, IN OTHER WORDS, QUALITY OF LIFE COULD STAND MUCH IMPROVMENT,

FURTHER TESTS (MRI - CTSCAN) HAVE PROVEN INCONCLUSIVE RESOLTION OF ITP PROBLEM

I HAVE BEEN INFORMED BY DR [redacted], THAT ~~YOUR~~ A COMPANY HAS DEVELOPED A DRUG (AMG 531) THAT COULD IMPROVE MY DAILY ~~LIFE~~ QUALITY OF LIFE.

I IMPLORE YOU TO TRY TO FAST TRACK THE TESTS ON THIS DRUG AND DO ANYTHING POSSIBLE TO GET THE FDA/AMA TO APPROVE THE USE OF THIS DRUG.

I FEEL MY TIME IS RUNNING OUT.

PLEASE

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 26, 2008 8:39 PM
To: Vesely, Nicole; shanin2auburn@yahoo.com
Subject: re: Oncologic Drug treatment for ITP

To Whom This May Concern:

I am writing this letter regarding the proposed treatment of ITP for consideration by the FDA to become an acceptable form of treatment for ITP.

My hope is that the therapy in respect to the treatment for ITP will become approved by the FDA as an effective form of treatment for those who suffer from this disease. I can only begin by telling you what my life was like before the study known as Amgen-531, and what it has been like during the study, as well as what I wonder what it will become if this drug is not approved by the FDA.

My life before this study: As a survivor of CML/post stem cell transplant, for whatever reason, my platelet count 12.4 years post transplant, had yet to recover. My life before I was placed on this study revolved around weekly, maybe bi-weekly, occasionally, but rarely monthly platelet transfusions. I lived with a platelet count, that if I had 11,000 platelets, that was a good week; however, if my platelet count was 10,000, I had to make arrangements to receive a platelet transfusion. Some transfusions have been better than others, in the respect that maybe I would get a good bump to increase my platelets, but maybe I wouldn't. Also, to avoid a serious reaction from donor platelets, I would receive 50 mg of Benadryl, as well as Decadron as preventative premeds. My reactions include but are not limited to an acceleration in my heart rate due to the medications, as well as spasms in my lower back, but without the premeds I break out in head to toe hives, which take several hours to subside.

Of course there is another aspect in how needing to receive donor platelets affect my life. Because of the premeds, the Benadryl causes me to have fatigue and headaches; the Decadron causes me to not be able to sleep, and therefore I would have lingering fatigue as well as headaches from lack of sleep. Then again too, despite receiving the premeds, I have experienced break through reactions to the donor platelets, that have included itchy eyes, as well as head to toe hives.

The difference in receiving donor platelets vs the study medications has been night and day, just in the time alone that it takes from start to finish. In the past, days I would receive platelets, it would not only take about two hours to receive the premeds and donor platelets, but I would also lose precious time with my family, as I would be too tired to stay awake (from Benadryl), and too wired to sleep (from Decadron). However, the stark difference is that with the new therapy, I walk in, have labs drawn, get my injections, and I'm done. Not only is time a factor, but also the bruising. For years I have bruised so incredibly easily. We always say the wind could blow past me and I would bruise, but in reality, things that normally wouldn't cause others without ITP to bruise, I do.

My quality of life has improved since I was placed in this drug study.

1. I have less bruising and bleeding
2. I have been less dependent on donor platelets
3. Fewer platelet transfusions has resulted in no reactions from donor platelets.

I need this drug to become FDA approved because without it, I go back to needing donor platelets, and I go back to waiting for donor platelets to become available; whether it is waiting for the blood bank to receive them, or waiting for my doctor's office to receive them from the hospital because the donor platelets are on hold for open heart surgeries. I go back to wondering if the donor platelets will help, or have I become refractive from receiving too may transfusions.

As compelling as it may seem, one cannot put themselves in my shoes, watching, waiting, wondering after twelve plus years of being platelet depend ant whether a new therapy will come along, or is this the

best that I am ever going to get.

I urge you, for myself and others with ITP, to look at all the data, but also see the human factor on how this treatment is effective for those with ITP. It has not only been effective, but also, going back to a life of having to receive donor platelets; while a blessing in and of itself, is not a great quality of life considering the medications to prevent reactions as well as those side effects, and of course the break through reactions. Donor platelets are only effective for so long. This treatment has hope, and it has promise to move from platelet dependent to better. It is the difference between going backward or moving forward.

It is my sincerest hope that the FDA looks intently into the research data as well as the patient testimonials in the consideration for the medical treatment for ITP.

Sincerely,

[redacted]

[redacted]

February 16, 2008

Hello! my name is [redacted]
a 84 year "young" lady with chronic I.T.P. since 2004.

I was a healthy, vibrant woman until a very serious auto accident (trauma) on [redacted]

Upon [redacted] my platelets rose to 528, in 9 months time I fell short of adequate. I also have had an inadequate response to corticosteroids. I receive [redacted] infusions every two weeks, and at the end of the two weeks, my platelets are in the range of 3 to 10, twenties, thirties, but mostly ten or under. Three doctors have told me they feel I am a good candidate for the new treatment.

I eat well, sleep fine, very active and up beat, but it is a real battle to know every two weeks my life is challenged by two days, five hours a day confined to a hospital bed

getting [redacted] infusions, to add to my "HELL", I have very small veins making thy infusion dreadful. I have very little bruising, had two bad nose bleeds, received blood transfusions, platelets, and "NOW" it is TIME" for yay thy "F.D.A" to step up and "APPROVE" what is known as "Rommplostin" or "A.M.G 531/N PLATE" which has already helped those who have been in thy trials and offer a better quality of life to myself and many many achey folks. "HOPE" is strong in our body and minds that thy F.D.A. will put itself in our situation (your parent, sibling, friend) and grant us a chance to prove a scientific accomplishment was "thy" force that gave us thy chance to live a fruitful life, from infants to myself, & young in mind, heart and body, 84 year old wife of [redacted] years, mother of two beautiful girls, a lovely granddaughter and many cherished friends. "HOPE"

Thank you for the opportunity

to address you by letter and please excuse my fancy corresponding stationary.

I will be happy to hear from you, a big "Happy Response" will be welcomed

"Chance" gave me this horable disease but "Hearts" can make us "freends"

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 6:15 PM
To: Vesely, Nicole
Subject: NPlate (AMG531) Review

To Whom It May Concern:

I was diagnosed with ITP in 2005. In the past two years, I have endured the following treatments:

Prednisone
Danazol
[redacted]
Rituxan
Platelet infusions
[redacted]

The results of these treatments were temporary or negative, and some had unpleasant side effects. It seems that present treatments are borrowed from other illnesses with limited results.

The results of AMG 531 seem very promising, and I believe it would be an injustice to all potential patients to deny access to this product.

I hope the FDA does the right thing by approving this drug. If approved, my family and I will thank the FDA.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 26, 2008 11:56 AM
To: Vesely, Nicole
Subject: AMG 531

Nicole,

Hi! My name is [redacted] I have been on the study since last April. My counts have been up and down each week depending on my dose. I have had ITP for 25 years, and this is the first drug that has helped keep my count up to a safe level. I have tried everything avaiable for ITP. I have had [redacted] and worry all the time about if I will have another one and not live through it. This drug has taken away the worry. I pray that the FDA will approve the drug so I can get on a stable dose. My doctor feels that I need 2.5 mics every week and on the study that is not an option. Plus I have to drive [redacted] every week to the doctor at about [redacted] a week charge for my visit. Please approve AMG 531 soon. Thank you and God Bless!
[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 26, 2008 2:02 PM
To: Vesely, Nicole
Subject: AMG 531

Ms. Vesley,

My name is [redacted] and I am the daughter of [redacted] At an early age I learned how scary ITP can be. I can remember spending many days and nights in doctor's offices and at hospitals wondering if my mom was going to be around to see me grow up. As a little girl and young woman it was very difficult watching my mother go through [redacted] chemo therapy, and medicines that continuously failed. Once I turned 18 I moved away to college and not a single day went by that I didn't worry or expect to get the dreadful phone call that my mom was in the hospital again. Then one day I received a phone call that there was finally a medicine that actually caused her platelet count to go up. Ever since that day I can breathe a little easier knowing that another brain hemorrhage is not likely. I just want you to please take my mother into consideration during this time. Approving this drug soon would truly be an answered prayer. Thank you for your time.

Best,
[redacted]

Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane (Bldg 5630)
Rockville, MD 20857

2/25/08

To whom it may concern,

I am writing in regards to the FDA approval of the drug AMG 531 (also called NPLATE and romiplostim). As a patient that has been using this drug for over 2 years, I want to encourage you to approve this drug along with the self-injection procedure.

I was diagnosed with ITP in December 2004 and tried many treatments to increase my platelet count. Those treatments include IV Rutiximab[redacted] high dose steroids (both Dexamethasone and Prednisone). Most of these treatments worked in the short-term, but not without side effects. After six months of these treatments, I had[redacted] hopes of reversing the ITP. After two months, my platelet count was back where I started.

I first received AMG 531 in August of 2005. By mid-October of that year, I started to respond to this treatment and by February 2006 I began the self-injection procedure. I have had no side effects from AMG 531 other than a platelet count that allows me to live my life without a worry of bleeding problems. This treatment is very easy and convenient. I was apprehensive in the beginning about self-injecting, but with proper training, it is a simple procedure. The self-injection procedure allows freedom from doctor's visits (other than once a month) and flexibility. It also allows the patient to feel as if they are in control again. With the success that I have had with AMG 531, I would not hesitate to recommend this drug to other ITP patients as an alternative to all the other treatments.

I want to strongly encourage the approval of this drug and injection procedure for myself and others like me. There are over 20 million people in the United States alone that have diabetes and more than 20% of them inject themselves daily with insulin. AMG 531 should be no different. We will still be routinely monitored for proper use, but with the freedom and control of our own lives.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Thursday, February 14, 2008 4:55 PM
To: Vesely, Nicole
Subject: Amgen 531

Follow Up Flag: Follow up
Flag Status: Red

Dear Nicole,
I cannot attend the meeting in Maryland of the FDA because I live in [redacted]

I am 70 years old and have had ITP since I was a child, receiving [redacted] at the age of eleven.
I had a few years of remission, [redacted]
and have been totally refractory the past two years.
My hematologist has tried Rituxan, Cytoxan, high doses of steroids which make my life totally intolerable and [redacted] The [redacted] works for approx. one month and is [redacted]

My platelets have been as low as 2000 and seldom get higher than 20,000, I have been waiting for Amgen 531 or Eltrombopag for several years and I am praying that the FDA will approve both of themj.

Sincerly,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 13, 2008 12:26 PM
To: Vesely, Nicole
Subject: March 12 neeting Re:Amgen 531

Dear Nicole,
I am 72 years of age and was diagnosed with ITP 21 years ago.
I have used all the conventional therapies - prednisone, [redacted] immunosupressants, cytoxin, rituxin, decadron pulses, cyclosporin. These either didn't work or stopped working for me. For the past 16 months, I have gone back to 20 mg. a day of prednisone, which is working for now, but has caused me to develop osteoporosis and is not a long term solution.
I have asked my hematologist [redacted] to apply to Amgen for compassionate use of 531 for me.
I am a member of The Platelet Disorder Support Association and members who have participated in the clinical trials have had success with 531 and have been able to get off prednisone
I am not able to attend the meeting on March 12th, but I ask the FDA to make this medication available to me and others who need a new solution to living with ITP.
Sincerely,

[redacted]

Date: February 25, 2008
To: FDA Representatives/ Michelle Vesely
Fr. [redacted]
Re: Amg531 vs. Alternative

I would like to thank you for this opportunity to at least put into words what a drug such as AMG 531 would mean to men and women like myself that are struck with this disorder known as ITP.

Our lives can change instantly both physically and mentally as this culprit ITP takes over our body. We watch our bodies and minds change in their abilities to do their everyday tasks. Not only does this disorder threaten our lives, given the right situation, but treatment options are invasive, mind altering, and physically drain a human being of strength. Therefore, job performance (if one could even go to work), physical capabilities, mental capacities, are stripped from one's attributes.

To understand and simply comprehend that the possibility of a newly researched and trialed drug such as AMG 531 has been made available and to my knowledge, now is in the hands of the FDA for approval, gives those afflicted hope of living a "safe" and "normal" life.

This would mean less chance of hemorrhaging to the brain, less massive nose bleeds, less time in the hospital (my stay ov[redacted]at a cost of ?), less sores in one's mouth, less cases of thresh and ulcers in one's mouth, less use of the steroidal drugs that have both long and short term affects on the mind, bones, sugar and adrenal balance, dangerous blood pressure and general welfare of the patient.

To imagine such research could alleviate the invasive affect not only of ITP as a disorder, but the present "invasive" treatment that must be used to even somewhat control it is so exciting. PLEASE.....review the trials and responses along with the minimal side affects of AMG 531 and..... Understand the significance of your approval. Your decision will be paramount in the lives of millions, and that decision will affect those individuals ..... IMMEDIATELY!

MERCY

ST. JOHN'S MERCY
DAVID C. PRATT CANCER CENTER

Nicole Vesely, Pharm D
LT, United States Public Health Service
Advisors and Consultants Staff HFD-21
Center for Drug Evaluation and Research
Food and Drug Administatration

Dear Dr Vesely,

February 26, 2008

We would like to submit a history and course of treatment for a patient that has participated in an Amgen 531 trial.

The patient has a long history of ITP, initially diagnosed in 1992. The patient presented with a platelet count of 65,000 and her bone marrow biopsy was consistent with ITP. For a time her platelet count was maintained on low does prednisone without any bleeding episodes reported.

Unfortunately, in [redacted] the patient was [redacted]s. At this time her platelet count fell to 18,000. The patient responded to corticosteroids but was unable to be tapered. The patient was subsequently treated with [redacted] but was still unable to be weaned from steroids. She developed subconjunctival bleeding and [redacted]. Her platelet count again responded initially but only for a short time. She was treated with Rituxan but did not respond.

By the end of 2006 the the patients platelet count was consistently below 10,000 and she was experiencing rectal bleeding. Her quality of life was significantly compromised and she was thrilled to learn of the Amgen 20040209 open label study for Severely Refractory ITP patients. The patient met all eligibility criteria and was enrolled in March of 2007. By April the rectal bleeding had resolved and by September the patient's platelet count was consistently above 100,000.

The patient is now self-injecting AMG 531 and coming in for visits monthly. Her platelet counts have stayed in the 150,000 range and she does not report any adverse events from the study drug. She has been able to resume her active lifestyle and travel to see her out of town family.

We would like to thank you for taking the time to read this testimonial. We hope this information will be helpful to your committee.

Sincerely,

[redacted] RN/CRC

Dr Bethany Sleckman, Principal Investigator
Dr Burton Needles, Sub-Investigator
Anne Fitzgerald, RN, Clinical Research Coordinator
[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 19, 2008 11:36 AM
To: Vesely, Nicole
Subject: AMG 531

February 19, 2008

Nicole Vesely
LT, United States Public Health Service
Advisors and Consultants Staff HFD-21
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane (Bldg 5630)
Rockville, MD 20857

Dear Ms. Vesely,

I know that AMG 531 is being considered for approval by the FDA. I'm glad to have an opportunity for input. I hope it is approved and I am thankful to have been able to be part of this clinical trial.

I wish it had been available sixteen years ago. It would have saved me the misery of taking massive doses of steroids and the pain of having [redacted], all for naught. My platelets have been as low as 3,000, but since taking AMG 531 have remained within normal range.

If I needed surgery before taking the AMG 531, I had to be infused with platelets and then rushed to surgery because the platelets don't last very long.

If it isn't approved, I'll have to go back to hoping that each day is my "lucky day" and that I won't need emergency surgery or have internal bleeding. I won't go back to taking steroids. I had severe leg and foot cramps and I couldn't think clearly. I couldn't go through that again. I was just too miserable. I'm not aware of any side effects from taking the medication. It's just too simple to take an injection once a week and have the knowledge that my platelets are within normal range.

I have been [redacted] at one point because I have ITP.

I hope this medication will make a difference, too, to newly diagnosed and particularly younger patients. Hopefully, their doctor will know about this treatment and give them the option of taking AMG 531.

Sincerely,

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Wednesday, February 27, 2008 9:14 PM
To: Vesely, Nicole
Subject: AMG 531

I was diagnosed with ITP July 15, 2007. I have been perscribed numerous drugs to increase my platelet count. All drugs had an inadequate response. I was [redacted] That too resulted in an inadequate response. Three weeks ago my platelet count was 24,000. I urge you to do whatever possible to get this new drug approved. For me medical options are running out. I have been told by doctors at the [redacted] that the severity of my platelet disorder is rare and there is nothing left to try. Again, please get this new drug approved.

[redacted]

February 10, 2008

To whom it may concern:

My name is [redacted] and I work as a [redacted] I have had the opportunity to work with Amgen Inc. in the clinical trials of Nplate (romiplostim) for over 6 ½ years. [redacted]s a small state and we have not enrolled the majority of the patients in any of the Amgen trials, yet I feel that my patients' experiences should be shared.

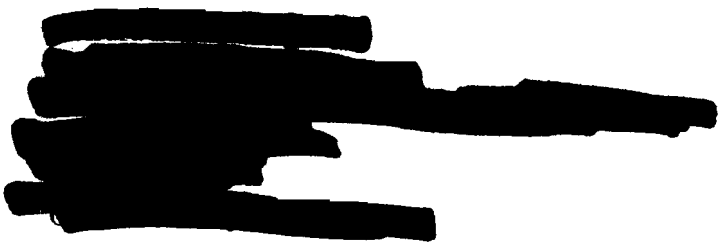
I believe Nplate (romiplostim) has actually changed lives. The most dramatic life changes have been in those patients with chronic refractory ITP. Patients who failed splenectomy and were faced with the choice of living with severe thrombocytopenia (platelet count < 20,000 μ/L) or getting periodic IVIG or Rituxan infusions. Besides the constant worry about bleeding if they were involved in an accident, they also worried about bleeding when they got their teeth cleaned, bleeding excessively from a skin biopsy, bleeding from a colonoscopy, or bleeding from any other outpatient procedure a person with a normal platelet count takes for granted. Since taking Nplate (romiplostim) these patients are able to get these routine medical procedures done without worry because they know their platelet count is in a 'safe' range. Additionally, patients (both men and women) constantly comment to me that they no longer have unattractive bruises. They love being able to wear short sleeves and shorts in the summer like everyone else. Women who suffered from menorrhagia now have menstrual cycles comparable to before they were diagnosed with ITP. I have had patients comment to me that now that they have been on Nplate (romiplostim) they sometimes forget they have ITP.

Besides the effectiveness of Nplate (romiplostim), my patients have not experienced any side effects. When you compare Nplate (romiplostim) to other standard treatments for ITP, Nplate (romiplostim) wins hands down. There's no weight gain or mood swings like with steroids, no headache for 1-2 days after like with IVIG, no long 3-4 hour infusion at the chemotherapy clinic like with Rituxan. Also, the ease of self-administration with Nplate (romiplostim) is amazing. The entire self-administration from start to finish (withdrawing the diluent, injecting the diluent into the Nplate and swirling until it dissolves, switching syringes, withdrawing your dose, and injecting) takes less than 5 minutes. Even my patients whom at the beginning thought they were not going to be able to self inject because they 'hate' needles, are self-injecting like professionals. For some patients it takes 3-4 times before they get comfortable, but by the 4th time they all have it down without a problem. There are no problems with compliance. They each know which day of the week they are supposed to inject on and that they can inject on that day, the day before, or the day after. The biggest problem with injecting the correct

dose is training the patients on how to look for air bubbles in the syringe. But again, after the first couple of times they know what air bubbles look like and are able to expel them. My patients' doses range from 0.2 ml to 2.2 ml and they are all able to self inject without a problem. The patients love that they only have to come to the doctor's office once a month, and for this reason they know they have to be compliant the other 3 weeks while they are home or their platelet counts might not be in the range allowed for self injection and then they would have to come to back the next week. No one wants to do this, so they are really diligent about injecting on the correct day and with the correct amount.

Finally, Nplate (romiplostim) helps ITP patients. ITP patients often feel neglected by their physicians. They are diagnosed with a 'benign' autoimmune blood disease not by a diagnostic test but by elimination of other diseases. The doctors try to answer their questions but the real question of 'why' the doctors cannot answer. Then they are told that the treatments available to them all have pretty significant side effects (most of the time these side effects are worse than the disease itself) and the only treatment that offers a cure is a surgery. If splenectomy doesn't work there are not many options, and these patients feel hopeless. Their doctors are caring for 'really sick' patients with cancer, and they don't want to complain about feeling fatigued or about being covered with bruises. So they live their lives with a low platelet count, avoiding aspirin and wearing their seatbelts. Nplate (romiplostim) gives these patients another option. Our patients who for years were without hope now have hope. Furthermore, Nplate (romiplostim) gives patients who don't want to have a splenectomy an option. The 6 ½ years that we have been enrolling patients and following protocols was all for this moment and it's exciting. Although I am not a physician and my words may not matter, I wanted to take the time to share with you the experiences of my patients. Thank you for your time.

Sincerely,



[redacted]

ATTORNEYS AT LAW

[redacted]

[redacted]

www.pensacolalegal.com

February 27, 2008

Ms. Nicole Vesely
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20857

VIA EMAIL
nicole.vesely@fdahhg.gov

Re: FDA Approval of AMG 531

Dear Ms. Vesely:

I am writing in response to the notice of a meeting held by the FDA regarding approval of the trial drug AMG 531 (Nplate). I have ITP and was diagnosed with the condition late summer of 2007. I had lower platelet counts as early as 2001, but it was not until the spring of 2007 that the levels began to drop and I was referred to a hematologist [redacted] with [redacted], for further review and testing. (My hematologist now is [redacted] with the same group.) The doctor had various tests done to try to rule out known causes for the low platelets and none were found.

When my platelet level dropped below 20,000 in September, 2007, the doctor placed me on a regimen of corticosteroids, in this case, prednisone at 80 mg per day. I was unresponsive to this treatment and my platelets continued to drop. When it was discovered my platelet level was 4,000 I was [redacted] I was first given a transfusion of platelets to try to determine whether the condition may have been caused by a virus. When I did not respond to the transfusion of platelets, I was given [redacted] and 3 IV treatments of steroids.

After receiving this treatment my platelet counts rose to acceptable, safe levels; however, after approximately 2 weeks, the level dropped again to between 2,000 and 4,000 and I was again admitted to the hospital with the same treatments. At this point, the hematologist started me on 1 of 5 infusions of Rituxin, 1 per week. I was unresponsive to the Rituxin. Every two weeks my platelets dropped below safe levels and I was again admitted to the hospital for infusions. These hospital admissions and treatments continued every two weeks until the first week in [redacted]

In addition to the foregoing, I received 1 treatment of [redacted] which did not raise my platelet level. After the [redacted] treatment failed, [redacted]

[redacted] upon doctor's recommendation. Unfortunately, that too was ineffective and I was [redacted] o receive the infusions two weeks after the spleenectomy.

After I was unresponsive [redacted] my hematologist, his medical staf[redacted] [redacted] taff and I researched on-going clinical trials, which included the AMG 531 trial. [redacted] located the trial at the [redacted] conducted by [redacted] and the clinical trial coordinator [redacted] I first visited them in late December. I was approved to be placed into the trial beginning in January of 2008.

After the first injection of AMG 531, I had a positive response. My platelet level first rose slowly, receiving 1 injection per week, and then quickly jumped to normal levels. My latest reading was 325,000, well within normal range. I have had no side effects that I am aware of from receiving AMG 531.

Treatment with this drug has made a significant, positive improvement in my quality of life. Anticipating every 2 weeks that my platelet level was to drop, which included bleeding episodes, and then being in the hospital for 3-4 days every two weeks to receive infusions, was extremely disruptive, tiring, and discouraging. Further, the side effects from the steroids were as bad, if not worse, than the ITP. These side effects included blurred vision, foggy thinking, weight gain, extreme fatigue, muscle cramps, and sleep deprivation. With AMG 531, I have been able to wean down to small levels of prednisone, which I should be able to be completely off of 6 weeks from now. The side effects from the prednisone have now almost disappeared.

My experience with AMG 531 has been nothing short of life changing and I sincerely hope the FDA, after looking at all the evidence, approves this drug for labeling and commercial sale.

If you have any questions, or desire any other information from me regarding my experience, please feel free to contact me. Thank you for your consideration.

[redacted]

[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 26, 2008 5:08 PM
To: Vesely, Nicole
Subject: ITP experience & amgen 531

Dear Committee,

I am a 22-year-old ITP patient, diagnosed when I was 19 during my sophomore year at [redacted] with a platelet count of 2,000. I would like to share my experience with ITP and Amgen 531 study drug. Prior to my enrollment in the clinical trial of Amgen 531, I have tried numerous drug options. I responded well to [redacted] at first, but later developed severe reaction that stopped me from ever taking it. At times prednisone and decadron would temporarily boost my platelets, but the side effects of "moon face" and difficulty falling asleep at night were really hard to deal with. At last I tried Rituxan; but when I was up to my 3rd dosage, I started to develop serum sickness that caused my knees very sore and swollen. Subsequently, I was [redacted] It really seemed like I was running out of options, therefore, my hematologist encouraged me to enroll in the Amgen 531 study about 2 years ago. I am really grateful for the period of time I have been on the study, my platelets have been stable in the range of 90,000~200,000 most of the time. I also never experienced any noticeable side effects, and my other cell counts also remained in the normal ranges. I am ecstatic that I can avoid constant hospital trips, and stop struggling to maintain a stable platelet count. Because of my stable platelet counts, I am even more confident to keep pursuing my career goals and excited to start medical school this fall. I believe that Amgen 531 would be a great option for many ITP patients.

Sincerely,
[redacted]

Vesely, Nicole

From: [redacted]
Sent: Tuesday, February 12, 2008 10:13 AM
To: Vesely, Nicole
Subject: Public Hearing March 12, 2008

Dear Ms. Vesely;

I am unable to attend the public hearing March 12, 2008 but I urge the FDA approval of the drug AMG531 known as Romniplostim for the treatment of ITP. I was diagnosed in January 2005 with ITP, I have anxiously been awaiting an alternative drug other than steroids, which I refuse to take. Please provide another option and I will make an informed decision as to the risks.

Thank you in advance for your time and every consideration!

[redacted]