Dr D's Study Group

STI GAZETTE # 1 Nov 1999

GATHERING OF THE GROUP:

The third gathering was November 1st at OHSU. Our first was a lunch at Oswego Pointe this summer. Our second a dessert at the same place. Being at OHSU will make it easier for all to attend. Since more of us come in on Mondays, we will be meeting the first Monday of the month in the Conference Room on the 14& floor at OHSU from 1-2:30. We hope that all of you coming to town will try to stop by to meet the others in this program.

PERSONAL MESSAGE: Brian Druker, MD

I would like to take this opportunity to thank each and everyone of you for your participation in this study. Please also extend this thank you to your families for their support. I know that many of you have traveled a great distance to take part. As I am sure you are aware, we are trying very hard to move this project along as quickly as possible so that anyone who needs this medication can have access to it.

For our studies of patients in accelerated phase and blast crisis, we now have centers throughout the world. This includes 2 in England, 2 in France,3 in Germany and 2 in Italy. In addition, centers are or will be opening in Boston, New York, and Detroit.

To say that 1 am pleased by how well this medication is performing would be a huge understatement. I have confidence that 5T1571 will become part of the standard of care for people with CML. Someday, when you or your family reads a textbook about this disease and see this drug mentioned, by whatever name it is eventually given, you should take great pride in knowing how much you will have helped other people with CML. This study has also validated one of the most important concepts in cancer research. That is, by understanding the difference between cancer cells and normal cells, we can create more effective and less toxic treatments.

In the case of CML, the Philadelphia chromosome was the obvious target and the product of the Philadelphia chromosome is what 5T1571 targets. By applying this to other cancers, it is my hope that there will soon be many other examples of drugs like this. Again, you have been the pioneers for the future of cancer therapies.

STUDY PERSONNEL:

Meet some of the other people at OHSU who are important to this study.

Carolyn and Melanie are the Clinical Nurses for Phase I and Phase II.

Dan transcribes the clinical research into forms that go to Novartis. He may have drawn your blood.

Michele is the administrative assistant. She'll help with your record keeping.

Supported by Leukemia & Lymphoma Society

ASH CONFERENCE:

Dr Druker will be presenting the findings of this drug study at the American Society of Haematologists December 5th in New Orleans. Following that conference we would expect to see and hear much about this study in the media.

DECEMBER GROUP MEETING:

We will be having our next group meeting the day after this presentation, December 6. It should be exciting. Come if you are in town. OHSU - 14th floor conference room from 1 - 2:30 pm.. Bring your lunch if you wish.

NEWS FROM THE GROUP:

From Dori: Just spent a week hiking in the Steens Mt and exploring Eastern. Oregon. Got caught in snowstorm leaving Bend.

From Joany: Judy organized a Portland support group. We benefitted tremendously. We met in a conference room here, and Dr. Druker met with us. I had goose bumps the whole time - excited by the beautiful stories we were hearing from the patients on their experiences with the *'Druker pills,* "and having Dr. Druker sharing information. Gerry is also doing well. His white cells have been normal for quite some time, but the platelets have been a challenge.

From Peter: After two years absence from her pottery (as well as her weaving and spinning), Rita is back throwing pots with abandon, thanks to
STIS71.

HUMOR: Did you hear about the tatoos on someone's fanny for a bone marrow test?.

PICTURES:

Dr Druker would appreciate pictures of his study people doing things they love to do. Some Doctors have a hard time visualizing that we can be healthy and active while on any medication that does what this does. So send pictures to Dr D.

PERSONAL PROFILE:

Hi, my name is Sandy. I live in London, UK with my partner David and our 14 year old daughter Nina Before my diagnosis in Jan '99 I was making ceramic art and painting a little too.

I was diagnosed when already in accelerated stage, and also had the complication of extensive myeloflbrosis. I refused conventional medicine and tried an alternative method based in Italy called the Di Bella Method. This has had some success with other cancers and leukemia, but less with myeloid leukemia.

I was lucky enough to have a related match (my younger brother) and was about to embark on a mini allograft at Hammersmith Hospital. I read of a Phase li trial of 5T1571 from Peter. I got on the trial in Portland. I am coming up to 3 months on the drug and being monitored by Hammersmith and OHSU. Hammersmith will start their trial when they have two patients in Phase Ill.

5T1571 has got me back to chronic stage from a frighteningly accelerating disease. I feel fortunate to have met and been treated by Dr. Druker, and to have met such wonderfully supportive people during my time in Portland.

Love and best wishes to all, Sandy.

TWO WORDS:

Rose: Kiss Druker
Blanche: Hug Druker
We love you Dr Druker. Thanks.

PLEASE SEND INFORMATION:

Please send any information you would like to pass along for the next newsletter. Send your Season's Greetings and keep in touch with others by letting them know some of what you are up to. Send them to Judy Orem at 5025J Foothills Rd Lake Oswego,

OR 97034 or email to jorem@flash.net.

There was a petition started by Suzana, of the Internet CML list, to encourage Novartis to increase production of STI 571. Over 7,000 signatures were collected and forwarded to Novartis along with a letter, greatly contributed to by our own Peter. I have included a transcription of a response from Novartis

Dear Ms. McNamara:

rm responding to the letter you sent to Dr. Daniel Vasella, Chairman and CEO of Novartis regarding the clinical development of the experimental agent STI *571,* which is being evaluated in patients with chronic myelogenous leukemia (CML).

Although the preliminary data is encouraging, STI 175 is still in very early stages of development and its safety and efficacy profile, as well as its optimal dosing, are currently being evaluated in three clinical trials in the United States and Europe.

Conscious of the impact this agent could have on patients with CML, Novartis has placed a very high priority behind expediting the compounds development with all diligence. Additional resources have been devoted specifically to substantially expand the drug production capacity for STI 571 in order to accelerate the clinical trial program.

Novartis is actively expanding the program moving forward into the next phase of development of this agent in patients with CML resistant to interferon. An international multicenter phase II study is planned that will open for enrollment in January 2000, if not sooner. This study will be initiated throughout the U.S. and Europe at sites experienced with treating patients with CML and able to meet the rigorous study protocol requirements involved with this agent. In parallel, Novartis is committed to continue the evaluation of the further potential of the compound in patients in accelerated phase and in blast crisis in the ongoing trials. In order to facilitate access to all of these trials Novartis intends to implement a centralized patient referral system. Discussions with the U.S. Food and Drug administration (FDA) regarding an expedited drug development and registration strategy for the compound have recently taken place resulting in the FDA granting Fast Track Designation for treatment of patients with CML in myeloid blast crises. Novartis is also collaborating with the Pediatric Oncology Group (a National Cancer Institute - sponsored cooperative group) on a protocol specifically designed for the agent's use in pediatric patients.

Currently limited by availability of drug supply, Novartis has devoted substantial attention to making sufficient quantities of the agent available as soon as possible. These actions include moving production of STI 571 directly to facilities usually utilized for commercial scale manufacture and increasing the technical resources and capacities devoted to the product. Novartis strongly believes that these efforts should make available more than sufficient supply of this agent for the expanded clinical trial program.

As a company committed to the oncology community and to patients living with this disease, I want to assure you that Novartis is taking every appropriate action to further expedite the compound's development in the interests of patients suffering from CML.

Sincerely,

James S Shannon