

**PATIENT INFORMATION ON VALCYTE TREATMENT
FOR CHRONIC FATIGUE SYNDROME—**

Richard Podell, M.D. May 30, 2007

In December, 2006 Dr. Jose Montoya of Stanford Medical School reported treating a series of twelve Chronic Fatigue Syndrome patients with Valcyte, a potent anti-viral drug. For the large majority, symptoms and functional activity improved dramatically during a six month treatment period. Reportedly nearly all have continued to do well. If confirmed, this could be an extraordinary treatment breakthrough.

Dr. Montoya selected patients who 1) had long standing CFS, neurocognitive symptoms, 2) and also high blood antibody levels against *both* Epstein Barr virus (EBV) and against Herpes Virus-6 (HHV-6). For ten subjects their CFS had begun with a “flu-like” illness. Two did not have a “flu-like” onset.

Nine of the ten “flu-like” onset patients improved dramatically with Valcyte. One did not. Neither of the two non-flu-like onset patients improved. A January 2007 press release from Stanford Medical School reported that Dr. Montoya had, by then, treated 25 patients. Of these 21 had gained major improvement. Again, improvement was confined to the patients whose illness had begun with “flu-like” symptoms. The press indicates that one of the successful patients has remained well, so far, for more than three years.

Caution—*This was an “open” not a double blind study.* However, spontaneous remissions and long-lasting placebo effects are not common with CFS, Therefore, I believe that Valcyte treatment is the probable reason for the dramatic improvement.

Valcyte is an oral medicine that is approved by the FDA for treating Cytomegalovirus (CMV) infection. CMV is a frequent problem among persons with AIDS or certain organ transplants. Valcyte is also active against HHV-6 and against EBV. HHV-6 and/or EBV are believed to cause a substantial proportion of chronic fatigue syndrome cases. The body converts Valcyte into a related molecule, another anti-viral drug, Ganciclovir.

Unfortunately Valcyte/Ganciclovir has potential for severe toxic side effects. These can be life-threatening.

Therefore, the decision of whether an individual with CFS should or should not treat with Valcyte requires balancing the (probable but not fully proved) potential gains against the potential risks.

Dr. Montoya's patients had no dangerous toxicity during their treatment. That may be because Dr. Montoya monitored his patients very closely, obtaining blood tests twice weekly for the first three weeks and then weekly over the six months of treatment. Medical visits were frequent.

In contrast studies of AIDS and organ transplant patients using Valcyte find that more than a quarter of those treated have to lower or discontinue their dose due to problems affecting the red blood cell, white blood cell or platelet counts. Stopping Valcyte or reducing the dose usually reverses the problems; but the potential for serious or even fatal complications is real. Valcyte/ganciclovir can cause cancer in animals. It is not known whether it causes cancer in humans.

In Dr. Montoya's study all the patients who eventually improved first had a period of worsening during the first month that lasted up to several weeks. In contrast, patients who did not later improve, did not have this flare-up. Probably the flare up was a "die off" reaction due to the breakdown of viral particles-- also known as a Herxheimer reaction. As such, an early flare-up with treatment may be a favorable sign, that improvement is likely.

Roche Pharmaceuticals has given Dr. Montoya \$1.3 to do a double blind study using Valcyte to treat CFS. Realistically, it might be two years or more before that study is completed and published. (That study is accepting patients, but only if they live in the San Francisco area.)

For the new study Dr. Montoya has added an important diagnostic test, a blood culture/antigen test to detect HHV-6 virus. (Commercially HHV-6 antibody tests are not highly reliable.) This new and better test is available from only one source at present, the Wisconsin Viral Research Group. Our office orders this test for patient whose commercial HHV-6 antibody tests are negative. (Unfortunately, the Wisconsin test costs \$495

and is considered “experimental” by some insurance plans, so might not be reimbursed.)

Our Policy on Valcyte Treatment for CFS:

We offer Valcyte treatment for selected patients who 1) are severely ill with CFS so that CFS greatly hinders their function and well-being 2) had a “flu like” onset of their CFS 3) fully understand the potential risks 4) promise, in writing, that they will faithfully adhere to the rigorous schedule for blood tests and medical visits and 5) have someone to care for them for several weeks if their symptoms flare during the initial part of the treatment.

We require blood tests twice weekly during the first three weeks. These labs should be done at our Summit office, since we receive these reports back by computer within 24 hours. After this blood tests are done weekly. These can be done at a laboratory near you. Patients will be seen in our office weekly for the first three weeks and then every two weeks. After improvement, some of these “visits” might be by telephone or with a cooperating physician near you.

We are considering how we can help persons who live far away. One option would be for our office to do the initial evaluation, to help decide whether you are a good candidate for Valcyte treatment. We might then consult with a physician near you, who you would select and who would actually prescribe and closely monitor the treatment. Collaborating physicians would have to agree in writing to the strict monitoring protocol. In theory this could work; in practice, it might not be easy to find a collaborating physician.

Our website (DrPodell.org) offers further information.

To read the abstract of Dr. Montoya’s December 2006 paper Go to the National Library of Medicine: [www. PubMed.gov](http://www.PubMed.gov). Enter in the search space the words Montoya Valcyte HHV-6. This should bring up the abstract.

To read the January 2007 Stanford Medical School press release go to:

http://med.stanford.edu/news_releases/2007/january/montoya.html

Also see these two useful sites The HHV-6 Foundation (link to www.hhv-6foundation.org) and The Wisconsin Viral Research Group (link to www.wisconsinlab.com)

To read Roche Pharmaceutical's FDA approved package insert on Valcyte go to: <http://www.rocheusa.com/products/valcyte/>. Then click on "complete product information" to read the formal package insert. Also click on "patient information" for a much simpler version.