

FOR EASE OF TRANSMISSION, THIS TRIAL PACKET CONTAINS TWO DOCUMENTS STRUNG TOGETHER. PLEASE DOWNLOAD AND SEPARATE THE DOCUMENTS, ESPECIALLY THE CONSENT FORM, WHICH NEEDS TO BE SENT BACK TO GenoMed.

DOCUMENT #1

LETTER TO PATIENTS AND PHYSICIANS INTERESTED IN GENOMED'S VIRAL ENCEPHALITIS TRIAL

PLEASE NOTE:

1. BACTERIAL MENINGITIS MUST FIRST BE RULED OUT WITH A SPINAL TAP. IF BACTERIAL, ANTIBIOTICS ARE REQUIRED OR THE PATIENT WILL DIE.
2. OUR TREATMENT WILL LIKELY NOT WORK FOR HERPES SIMPLEX ENCEPHALITIS. IF PRESENT, ACYCLOVIR IS REQUIRED.
3. OUR TREATMENT IS DESIGNED FOR WEST NILE VIRUS. IT CAN BE TRIED FOR EASTERN EQUINE ENCEPHALITIS (EEE), ST. LOUIS ENCEPHALITIS, HANTAVIRUS, ETC. BUT WE HAVE NO EVIDENCE THAT IT WORKS IN THOSE DISEASES.

Dear Prospective Trial Participant,

Thanks so much for your interest in GenoMed's clinical trial testing a possible treatment for West Nile virus encephalitis.

For some more background, please read the attached documents. We've also been issuing press releases since June, 2003 about our approach to West Nile virus encephalitis. They're available at our website (www.genomed.com) by clicking on "Company News" and then "Investor Information/Press Releases."

I want you to be absolutely clear that, at this early stage, I do not know for certain that our treatment approach will work for all patients, or for all stages of the disease. So I cannot make any guarantee whatsoever that GenoMed's treatment approach will work in your case.

This is who we think would benefit from our approach: Anybody who is ***NOT immunosuppressed***. Note: a person is immunosuppressed if they have leukemia, if they have an organ transplant such as a kidney or heart or liver transplant, if they take chemotherapy for cancer such as methotrexate (also used for psoriasis), if they take oral Prednisone (cortisone cream applied only to the skin is OK for our trial). Just being elderly does not make somebody immunosuppressed. So far, 6 of our 12 successful cases involve patients over the age of 70. ***Old age is NOT a contraindication for our trial.***

This is when we think an immunoCOMPETENT person should start our treatment:

When you develop a fever, headache, and/or muscle aches in an area known to have active West Nile virus infections. At this stage of the disease, it is called "***West Nile fever.***" Our goal is to try to keep the disease from progressing to a stiff neck (a symptom of meningitis) or confusion/coma/seizures ("West Nile encephalitis"). ***If it already has progressed to meningitis and/or encephalitis, our treatment should still be useful.***

Here are some representative numbers to give you an idea of the relative risks:

Total public at risk = 1 million people
People with mosquito bites = 10% of above (100,000 people)
People bitten by mosquitoes carrying WNV = 1% of above (1,000 people) **IN ENDEMIC AREAS ONLY**
People with viremia (WNV in their blood) = 15% of above (150 people)
People w/viremia but no symptoms = 80% of above (120 people)
People w/ fever, headache ("WNV fever") = 20% of above (30 people) **USE ARB HERE**
People w/ stupor/stiff neck ("WNV encephalitis") = 30% of above (9 people) **USE ARB**
Deaths (only from WNV encephalitis) = 10-30% of above (1-3 people; 10% risk if young; 30% risk if over the age of 50)

Please share these materials immediately with your physician so he or she can help you decide whether to participate in our clinical trial. Your physician must agree, since the drug we use—either an ACE inhibitor if your blood pressure is high, or an angiotensin II receptor blocker (ARB) at the lowest dose if it is normal—requires a physician's prescription. If you decide to participate, please print out and sign the Informed Consent and FAX it back to me. ***(For patients with low blood pressure, the smallest dose of an ARB pill can be cut in half and taken at bedtime to avoid lowering the blood pressure any further, e.g. half of a 4 mg candesartan (ATACAND) pill, half of a 50 mg losartan (COZAAR) pill, or half of a 40 mg telmisartan (MICARDIS) pill taken at bedtime should not lower blood pressure much at all).***

DOSE FOR HORSES:

COZAAR (LOSARTAN) AT A DOSE OF 1 MILLIGRAM PER POUND, ONCE A DAY FOR ONE WEEK. FOR EXAMPLE, A 1,000 POUND HORSE WOULD GET 10 X 100 MG PILLS OF COZAAR ONCE A DAY. EACH COZAAR PILL COSTS ABOUT \$1, SO THE PROTOCOL CALLS FOR ABOUT \$10 A DAY IN PILLS.

CONTINUE THE COZAAR FOR 7-10 DAYS. I.M. BANAMINE IS NOT RECOMMENDED, AS IT CAUSES STOMACH ULCERS.

We will issue ongoing press releases updating our experience in this unblinded trial, as we have done since late August, 2003. For ethical reasons, we're not insisting on a placebo control arm to this trial. That's because ARBs are extremely safe, but West Nile virus encephalitis is not. We see no reason to expose people to WNV without at least trying to do something to help them.

Our first eight patients were published in July, 2004—see Table 2 in:

Moskowitz DW, Johnson FE. The central role of angiotensin I-converting enzyme in vertebrate pathophysiology. *Curr Top Med Chem.* 2004;4(13):1433-54.

This reference can be downloaded as a PDF file by clicking on paper #6 at:
<http://www.genomed.com/index.cfm?action=investor&drill=publications>

Furthermore, our treatment approach to West Nile virus may be suitable for most viruses. It has been included in a recent version of the biodefense bill, BioShield II, now called S. 975: <http://www.govtrack.us/congress/billtext.xpd?bill=s109-975>
(See Chapter 5, Section 2151 for our proprietary approach to most viruses).

Please call or email me if you have any questions at all. E-mail is by far the fastest, cheapest, and most efficient way to get a hold of me.

Yours sincerely,

Dave Moskowitz MD, FACP
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DOCUMENT #2: WEST NILE VIRUS TRIAL INFORMED CONSENT

**USE OF ACE INHIBITORS OR ANGIOTENSIN II RECEPTOR BLOCKERS
IN THE TREATMENT OF WEST NILE VIRUS ENCEPHALITIS: A
CLINICAL TRIAL**

DATE: _____

NAME: _____

1. _____, working in collaboration with Dr. David W. Moskowitz of GenoMed, Inc., an American for-profit company, has requested my participation in a research study sponsored by GenoMed, Inc. This research could result in a profit for GenoMed, Inc. The title of the research is "Use of Angiotensin II Inhibition for the Treatment of West Nile virus encephalitis." THIS IS STILL AT THE LEVEL OF A CLINICAL TRIAL. THERE CAN BE NO GUARANTEE THAT THIS TREATMENT WILL BE AN EFFECTIVE TREATMENT FOR WEST NILE VIRUS ENCEPHALITIS. SPECIFICALLY, IT MAY NOT PREVENT DEATH FROM WEST NILE VIRUS. IT IS NO SUBSTITUTE FOR ANTIBIOTICS SHOULD THE PATIENT HAVE BACTERIAL MENINGITIS OR ENCEPHALITIS. BY SIGNING THIS INFORMED CONSENT, THE PARTICIPANT(S) AGREE NOT TO HOLD LIABLE IN ANY WAY GENOMED, INC. OR ANYONE ASSOCIATED WITH GENOMED, INC.

2. I understand that the purpose of this research is to see if West Nile virus encephalitis may respond to an ACE inhibitor or an angiotensin II receptor blocker (ARB). ACE inhibitors have been used for over 20 years to treat high blood pressure and heart and kidney disease. ARBs have been used for the past decade to treat high blood pressure.
3. My participation will involve being treated with an ACE inhibitor or an angiotensin II receptor blocker (ARB), and allowing my doctor to share the details of my medical chart with Dr. Moskowitz at GenoMed. GenoMed would like to follow how I do for at least one month.
4. I understand that there are possible risks to me if I agree to participate in the study, primarily the side effects of any ACE inhibitor. These include a dry cough in up to 10% of patients, swollen lips (“angioedema”) in up to 2% of patients, and, very rarely, suppression of white cells in 1 patient per 10,000. Side effects of ARBs are much less frequent. The major side effect of both kinds of drugs that my doctor will be monitoring is my blood pressure; too large a dose of the ACE inhibitor or ARB will make me feel dizzy or light-headed. If this occurs, the dose will need to be decreased, usually just cut in half. In any event, Dr. David W. Moskowitz can be reached by telephone at (314) 983-9933 or by email at dwmoskowitz@genomed.com or dwmoskowitz@hotmail.com.
5. My name will not appear in any publications or presentations of the results of the studies which are produced by this investigation.
6. I am aware that my participation in this study may be of no benefit to me, in other words, the ACE inhibitor or ARB I take may not help my disease.
7. I understand that the alternative is nonparticipation in this study.
8. I understand that my participation is voluntary and that refusal to participate will involve no penalty to me or loss of benefits to which I am otherwise entitled. I also understand that I may withdraw from this research study at any time without penalty or prejudice.
9. Any questions that I may have concerning my participation in this research study will be answered by Dr. David W. Moskowitz who can be reached at (314) 983-9933 or by email at dwmoskowitz@genomed.com or dwmoskowitz@hotmail.com.
10. I understand that GenoMed does not provide compensation to human subjects in the event the research results in physical injury; however, this does not mean I have waived my legal rights by signing this form.
11. I am aware that the purpose of this research is to learn more about the treatment of common, currently untreatable diseases, such as West Nile virus encephalitis. I am also aware that GenoMed, Inc. is undertaking this research because the

company believes it could result in a substantial profit for the company. At this time it is not possible to predict whether any new information will be obtained from this work, or, if obtained, what the nature of that information will be. As stated previously, it has been explained to me that the results of any studies will be maintained as confidential; the possibility of a break of confidentiality is rare, but not impossible. Every effort will be made to keep these records private.

12. I have read the above statement and I have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I believe I understand the purpose of this study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study.

Date

Signature of Subject

Printed Name of Subject

Signature of Witness

13. I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that may have been raised, and have witnessed the above signature.
14. I have provided the subject/patient a copy of this signed consent document.

Date

Signature of Investigator

PLEASE SIGN AND RETURN TO DR. DAVID MOSKOWITZ AT FAX 314-754-9772 or FAX 314-983-9939. OR SCAN AND EMAIL TO dwmoskowitz@genomed.com or dwmoskowitz@hotmail.com. THANK YOU!