

**MARQUETTE GENERAL HEALTH SYSTEM  
Regional Medical Center**

**CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY**

**TITLE: COMPASSIONATE USE OF RFS 2000 (9-Nitro-Comptohecic, 9-NC)  
FOR A SINGLE PATIENT WITH REFRACTORY PANCREATIC  
CANCER**

**Investigator:**

**Sponsor:** SuperGen, Inc.  
4140 Dublin Blvd, Suite 200  
Dublin, CA 94568

**INVITATION TO PARTICIPATE:**

Federal regulations require written informed consent from participants prior to participating in a research study, so that they can know the nature and risks of participation, and can decide to participate or not to participate in a free and informed manner. You are asked to read the following material to ensure that you are informed of the nature of this research study, and of how you will participate in it if you consent to do so. Signing this form will indicate that you have been so informed, and that you give your consent.

**PURPOSE OF THE STUDY:**

You have been told that you have pancreatic cancer within your abdomen and had previously been treated with other chemotherapy. The purpose of this study is to provide you the opportunity to receive the investigational (experimental) drug called RFS 2000 (Rubitecan, 9-NC). Investigational or experimental means that the drug, RFS 2000, has not been approved by The Food and Drug Administration (FDA).

**PROCEDURES TO BE FOLLOWED:**

Prior to starting study medication, you will have a complete medical history taken and physical examination including chest x-ray, electrocardiogram, and blood and urine tests will be performed. You will return for weekly evaluations including blood and urine tests during therapy. After every four weeks, you will have physical examination including blood and urine tests. If you have had a successful response to treatment, you may receive further oral doses of RFS 2000, unless toxicity is encountered, or if you are unable to tolerate the treatment.

RFS 2000 is in a form of capsules and given orally (by mouth). RFS 2000 will be administered at a starting dose of 1.5 mg/m<sup>2</sup> per day for 5 consecutive days followed by

2 days of rest. You will be instructed by your physician on how to take this drug properly.

### **DISCOMFORTS AND RISK:**

Based on previous clinical studies with orally administered RFS 2000, you will be closely monitored for the following potential adverse effects:

Suppression of bone marrow activity: This may result in decreases in the number of circulating white blood cells, and may cause you to be more susceptible to infections. Similarly, decreases in the number of circulating platelets may also result, and this may increase your likelihood of bleeding. Reports of gastrointestinal (GI; i.e., stomach, intestines) bleeding have been reported in a low percentage of patients tested to date. Some mild to severe gastrointestinal side effects have also been reported. These potential toxicities, however, have been demonstrated to be reversible when the drug is discontinued.

Miscellaneous: Other reversible side effects reported have included partial to total hair loss, cystitis (inflammation of the bladder), mild gastrointestinal side effects (abdominal pain, loss of appetite, nausea, vomiting, and diarrhea/dehydration), weakness, fatigue, back pain, and fever.

While every precaution will be taken to monitor for these adverse effects, you must notify the Investigator immediately if you experience any of the above mentioned.

Taking this experimental therapy may involve risks to you (or to your embryo or fetus if you or your partner, become pregnant), which are currently unforeseeable. While you are on this experimental therapy, if you are of childbearing potential, you must use an accepted contraceptive method.

### **BENEFITS THAT CAN BE REASONABLY EXPECTED:**

It is possible that the oral administration of RFS 2000 may result in shrinkage of the tumors caused by your cancer. We are, however, unable to guarantee a cure for this cancer as a result of receiving this investigational treatment. We can give no assurance that the use of this drug will be beneficial to you.

### **ALTERNATIVE PROCEDURES AVAILABLE:**

Other options may exist for the treatment of your cancer, including chemotherapy, radiation therapy, surgery, or a combination of these. Your physician will discuss these alternative options in detail, at your request. Significant new findings about RFS 2000 which may affect your willingness to continue taking this experimental therapy will be made available.

**ADDITIONAL COSTS:**

The experimental drug, RFS 2000, will be supplied to you free of charge. You, or your insurer, will be responsible for those costs that are not an immediate part of treatment. No commitment is made by the Investigator to provide free medical care, or compensation for any adverse results from participation in this experimental treatment. Medical services will be available at the usual costs.

SuperGen will not provide payment for expenses that are in any way attributable to the negligence or misconduct of any person employed by or acting on behalf of the Institution or your failure to follow instructions. SuperGen will not pay for hospital treatment or medical complications related to the natural course of the primary disease. No other type of compensation is made available.

For further information regarding the conduct of this experimental treatment plan, please telephone the Investigator, Dr. Arnold at (906) 225-3922. During evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the medical oncologist on call. Any questions you have concerning your rights as a research subject will be answered by the Department of Community Relations at Marquette General Hospital, and may be reached by phoning (906) 228-9440 and request to speak with a representative in that department.

**CONFIDENTIALITY:**

Your medical records related to this experimental therapy may be made available to the Food and Drug Administration, or to authorized representatives of the study's Sponsor, as provided by Federal Regulations.

**VOLUNTARY PARTICIPATION/WITHDRAWAL:**

Dr. Arnold will be available to answer your questions about the study at any time. Your participation is entirely voluntary and you may refuse, or discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled. Your decision about whether or not to take this experimental therapy will not affect the care that you receive.

Dr. Arnold or SuperGen, without your consent, may terminate your participation in this experimental therapy at any time.

For further information regarding the conduct of this experimental treatment plan, please telephone the Investigator, Dr. Arnold at (906) 225-3922. During evenings, weekends, or holidays you may phone Marquette General Hospital at (906) 228-9440, and request to speak with the medical oncologist on call. Any questions you have concerning your rights as a research subject will be answered by the Department of Community Relations at Marquette General Hospital, and may be reached by phoning (906) 228-

9440 and request to speak with a representative in that department. You will be given a copy of this consent form.

Your signature below means that you have freely agreed to participate in this medical experimental therapy.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date

Your signature below means that you do not wish to participate in this investigational study.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date

Expedited Emergency Approval: 01/22/04.  
IRB Approved 2/11/04  
Emergent Approval of Revision 03/30/04 PT