

## **What Will Happen If I Participate In This Clinical Trial?**

Before you can be in the trial, you must sign a consent form showing that you have been given information about this study and that you understand it. So make sure you understand all the information first and ask the person giving you the information to explain anything you do not understand.

If you participate in this study, you will be “randomized” into a study groups. Randomization means that you are assigned to a study group by chance. You will have an equal chance of being either in the RFA alone group or the RFA plus ThermoDox group. Neither you, your doctor, nor the researchers will be able to choose which group you are in.

## **What Are My Choices?**

Deciding to participate in a clinical trial is completely voluntary. You may choose to leave the study at any time for any reason. You may choose to discuss other treatment options with your physician, instead of participating in a clinical trial.

## **Is There Any Risk To Me?**

Every drug has side effects, your doctor will provide with all the relevant information to review before you decide to enroll in a trial.

## **What are the Potential Benefits?**

The clinical benefit will be determined after all patients are enrolled and analysis on the study results are performed.

### **Study Sponsor:**



10200-L Old Columbia Road • Columbia, MD 21046

# **Patient Guide**

## **HEAT Study**

Hepatocellular Carcinoma Study  
of RFA and ThermoDox

**Sponsored by:**  
**Celsion Corporation**  
**10200-L Old Columbia Road**  
**Columbia, MD 21045**

For more information  
consult your physician

Many patients have questions regarding their treatment options. This patient brochure is intended to inform you of an investigational drug currently in Phase III clinical trials at multiple centers worldwide for the treatment of hepatocellular carcinoma HCC.

## What Is The HEAT Study?

The HEAT Study is a clinical trial evaluating the effects of ThermoDox® in combination with radiofrequency ablation (RFA), by comparing it to the treatment of RFA alone in hepatocellular carcinoma (HCC).

## What Is ThermoDox?

ThermoDox is a heat sensitive drug that releases doxorubicin, an anti-cancer drug, when exposed to the heat of RFA. It is given through a vein.

## What Is A Clinical Trial?

Clinical trials are research studies designed to answer scientific questions that help doctors find better ways to prevent, diagnose and/or treat diseases.

## Who Can Join?

You may be eligible to join this study if you meet certain criteria. Only you and your doctor should decide whether your enrollment in a clinical trial is right for you.

### 1. What Is HCC?

Hepatocellular Carcinoma HCC is the 7th most common cancer in the world. It is also known as primary liver cell carcinoma. HCC is cancer that arises from hepatocytes, the major cell type of the liver. The most common contributing factors towards the development of HCC include viral hepatitis (especially hepatitis B and hepatitis C). Other factors include cirrhosis, hemo-chromatosis, and aflatoxins.

### 2. How is HCC Diagnosed?

- physical exam shows an enlarged, tender liver.
- CT scan reveals a mass in the liver.
- liver scan indicates an abnormality
- liver function test indicates that liver enzymes are elevated.
- Serum alpha-fetoprotein is elevated.
- liver biopsy shows HCC.

### 3. What Are The Stages of HCC?

**Stage I:** tumor does not invade blood vessels.

**Stage II:** a single tumor (any size) invades blood vessels, or multiple tumors less than 5 cm in diameter.

**Stage IIIA:** multiple tumors are present and at least one is larger than 5 cm in diameter, or a tumor invades a branch of the major liver blood vessels (portal or hepatic vein).

**Stage IIIB:** tumor invades a nearby organ (other than the gallbladder) or penetrates the lining of the liver.

**Stage IIIC:** cancer invades nearby lymph nodes. (Tumors can be any size or number).

**Stage IV:** cancer spreads to other parts of the body, i.e. the lungs, bones, etc. (Tumors can be any size or number, and nearby lymph nodes may or may not be involved.)

### 4. What Is Non-Resectable HCC?

Although many HCC cases are amenable to surgery, non-resectable means the condition is inoperable.

### 5. What Are The Treatment Options For Non- Resectable HCC?

Ablative therapy (eg, RFA, alcohol, cryotherapy, microwave) or a clinical trial investigating a new approach. Your doctor can discuss all of these options with you.

### 6. What is RFA?

Radio Frequency Ablation is a procedure that destroys liver tumors approximately 7 cm and smaller by heating them to temperatures between 80 and 100 degrees C using a needle and electrical current. This treatment may be used before and after surgical options to improve patient outcome. The length of the RFA procedure is proportional to the size of the tumor(s) involved.

### 7. What Is The Potential Benefit of RFA In Combination With A Chemo-Therapeutic Drug?

There may or not be a direct benefit to you if you volunteer for this clinical trial. Your health or condition may get better as a result of your participation, it may stay the same or it may get worse. No one can completely predict the outcome of a clinical trial or how it might effect you. The study may result in information that will help others in the future.

The concept behind the combination treatment in the H E A T Study is to extend treatment to the region beyond the immediate tumor into the zone that borders around the tumor and the rest of the liver. This combined approach increases the region of tissue that can be treated (beyond using only 1 form of treatment).