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Interventional Cryoablation Stops Cancer Cold—Curative Option for Patients With Small Localized Kidney Tumors

Washington, D.C. (March 17, 2008)—Two papers presented today at the Society of Interventional Radiology's 33rd Annual Scientific Meeting show that cryoablation—the minimally invasive interventional radiology treatment to freeze primary kidney tumors without surgery—is 95 percent effective when the tumors are four centimeters or smaller and nearly 90 percent effective for tumors up to seven centimeters, when the disease is confined to the kidney at one-year follow-up. The one-year benchmark is established and well-accepted within the medical community to gauge the success rate of a treatment option because most kidney tumors would be visible at one year with a CAT scan or MRI. "This interventional radiology treatment can effectively kill localized kidney tumors on an outpatient basis for most patients while offering a fast recovery time and an excellent safety profile," said Christos Georgiades, M.D., Ph.D., interventional radiologist at Johns Hopkins Hospital in Baltimore, Md. When the disease is confined to the kidney, the intent of treatment is curative. Using imaging to pinpoint the tumor, the interventional radiologist inserts a thin probe through the skin and guides it into the tumor below. The probe freezes and kills the tumor during the procedure.

The study at Johns Hopkins Hospital showed nearly 95 percent efficacy for localized tumors up to four centimeters and nearly 90 percent efficacy for tumors up to seven centimeters, with the lesions showing as dead tissue (scar) with no recurrences at one-year follow-up imaging. The ongoing study currently includes approximately 70 lesions in 60 patients with primary renal cell carcinoma. Of the three patients who failed treatment (5 percent), one had a 10-centimeter tumor that physicians did not expect to cure, but there is only one centimeter of residual tumor that they plan to re-treat when the patient returns. The other two failures were in patients with larger tumors (7–10 centimeters), and physicians plan to treat those two patients again. One has only a half-centimeter residual tumor 18 months later. Thus, the secondary efficacy (after re-treatment) is expected to be close to 100 percent.

"The current gold standard treatment is laparoscopic partial nephrectomy surgery, but given the high success of interventional cryoablation—that may change. We expect that the two treatments will be shown to be equivalent in a comparative study that is ongoing now at Johns Hopkins. The interventional radiology treatment is less invasive and easier on the patient," noted Georgiades.

In addition to the patients who have the smaller tumors of four centimeters or less, this treatment offers a potentially curative option for patients with localized tumors who are

not eligible for surgery. Many patients have other diseases that make surgery very high risk, cannot undergo the anesthesia and do not have any other option. Also, people with borderline kidney function, only one kidney or multiple recurring tumors had no options until now, he explained. "I want to get a message out, mostly to my colleagues, because they will encounter many patients who have these treatable cancers but they cannot have treatment or surgery because of other diseases. Until a few years ago, we in the medical community simply followed these patients; we didn't treat the cancer for fear we may make things worse if we try to treat risky patients. But for many patients that's no longer the case," said Georgiades.

This interventional radiology treatment spares the majority of the healthy kidney tissue and can be repeated if needed. The treatment is very safe, and most patients are sent home the same day as the procedure. The rest go home the next day. The most common complication is a bruise (hematoma) around the kidney that goes away by itself.

The study from Barbara Ann Karmanos Cancer Institute in Detroit, Mich., involved 65 people and 81 masses, of which 61 were primary renal cell carcinoma (RCC), 6 oncocytoma, 1 angiomyolipoma, 8 renal benign or inflammatory lesions and 1 metastatic lesion. The average tumor size in this study was 2.8 centimeters. At 1.3 years average follow-up time (0.2–5 years), the majority of tumors continue to image as dead tissue. In contrast to heat, the cryoablation zone continues to shrink after cryotherapy, reducing up to 90 percent in volume by 12 months without scarring or strictures. Only 6 percent (5 of 81 tumors) had a local tumor recurrence, and these were limited to patients with multiple tumors in the kidney or an early probe failure. It is crucial to use enough cryoprobes to get sufficiently cold temperatures to kill all tumors and extend the visible ice approximately one centimeter beyond all tumor margins, similar to a surgical margin. Complications are avoided by liberal use of saline to push away the adjacent bowel, allowing tumors in nearly any location of the kidney to be treated.

"This interventional treatment is not a widely known procedure yet, even to other physicians, and patients are going to have to pursue it on their own," added Georgiades. The treatment is widely available in the United States at all major institutions and some smaller institutions as well; it is usually covered by health insurance. The Food and Drug Administration (FDA) has approved cryoablation for use in soft tissue tumors, of which renal cell carcinoma is one. More information can be found at <u>www.SIRweb.org</u>.

Abstract 100: "Efficacy of CT-Guided, Percutaneous Cryoablation for Renal Cell Carcinoma: One-Year Follow-up," and Abstract 101: "Percutaneous CT-Guided Cryotherapy of Renal Masses: Long-term Follow-up and Morbidity," can be found at www.SIRmeeting.org.

About Kidney Cancer

Kidney cancer is the eighth most common cancer in men and the tenth in women. The most common type of kidney cancer is renal cell carcinoma that forms in the lining of the renal tubules in the kidney that filter the blood and produce urine. Approximately 85 percent of kidney tumors are renal cell carcinomas.

More than 32,000 Americans each year are diagnosed with kidney cancer—many of them don't have symptoms. Typically, those with kidney cancer are past the age of 40 and are

twice as likely to be men. Other risk factors include smoking, obesity, high blood pressure, long-term dialysis and Von Hippel-Lindau syndrome.

About the Society of Interventional Radiology

Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-ray, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease internally. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine. Interventional oncology is a growing specialty area of interventional radiology.

Today many conditions that once required surgery can be treated less invasively by interventional radiologists. Interventional radiology treatments offer less risk, less pain and less recovery time compared to open surgery. Visit <u>www.SIRweb.org</u>.

Local interviews and broadcast-quality video footage are available by contacting SIR's communications department at <u>mverrillo@SIRweb.org</u>.

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