

Embargoed for Release, Friday, April 1, 2005, 9 a.m. CT

**New Research Shows Three Innovative Nonsurgical Bone Tumor
Treatments Provide Pain Relief for Cancer Patients**

***Interventional Radiology Treatments Improve Quality of Life for Patients Living with
Cancer Who Have Debilitating Pain***

NEW ORLEANS, Louisiana (April 1, 2005) – Research shows that three new nonsurgical treatments reduced the severe pain caused by bone tumors by 74 - 89 percent, in patients that have failed conventional pain treatments. The studies were presented today at the 30th Annual Scientific Meeting of the Society of Interventional Radiology. These new nonsurgical techniques — osteoplasty, radiofrequency ablation and cryoablation — heat or freeze the tumor, which kills the tumor and nerve endings in the vicinity of the metastasis, that were causing pain. Cancer often metastasizes to bone, and can cause terrible pain that is unrelieved by narcotics and other standard pain treatments. These treatments could benefit many of the 100,000 people who develop bone metastasis in the United States each year.

“Pain affects greater than 60 percent of patients with advanced cancer and for many the pain is due to bone metastases, often destroying the quality of their remaining life. This research shows these new interventional techniques are effective to help these patients without surgery, and offer a short recovery time. The treatments work within weeks, are well-tolerated and can be repeated if needed,” says Interventional Radiologist Matthew Callstrom, M.D., PhD, Mayo Clinic, Rochester, Minnesota.

Painful bone metastases are generally not treated with surgery because it would not offer a cure, and would subject the patient to an extensive procedure and recovery time. The purpose of treating painful bone tumors is to reduce pain and improve quality of life. Currently, patients who are not helped by narcotics are offered radiation treatments to reduce their pain. Radiation reduces pain in approximately 70 percent of patients; however, the pain often returns or increases over time, and further radiation therapy is often not possible because it would damage healthy tissue. In addition, radiation therapy often takes 5-20 weeks to work. The new interventional treatments offer patients whose pain does not respond to narcotics or radiation, whose pain increases, or whose treatment options are exhausted, nonsurgical pain treatments that improve their quality of life and are easily tolerated.

“As a physician, it is particularly rewarding to treat these patients because we make such a difference in their lives. Many of these patients were disabled from their pain, unable to perform everyday activities without pain,” says Callstrom. “These new interventional treatments offer cancer patients a chance to feel more normal as well, without the constant reminder of their illness.”

About the Techniques and Studies

Cryoablation (Abstract 106) – Cryoablation offers a nonsurgical, localized treatment that kills the targeted tissue by freezing it with extreme cold produced by Argon gas in a sealed probe, while sparing the healthy tissue. Because of the localized nature of this treatment, it does not have any systemic side effects. In this procedure, the interventional radiologist uses CT and ultrasound imaging to guide up to 8 probes through the skin into the tumor, under anesthesia. The “ice ball” that is created around the probe, visible with CT imaging, grows in size and destroys the frozen tumor cells.

Cryoablation has been used for many years by surgeons in the operating room, but in the last few years, the probes have become small enough, and are now insulated, so that they can be used by interventional radiologists through a small nick in the skin, without the need for an operation or stitches.

This is the first prospective trial to evaluate the safety and efficacy of percutaneous (through the skin) cryoablation for palliation of painful metastatic bone lesions. These interim results in 10 patients show that relief of pain is significant, and the treatment can be safely performed. Of the 10 patients who have completed the 24 week follow-up, 80 percent had an average 74 percent reduction in their worst pain. The study is ongoing and a total of 30 adult patients are planned for enrollment.

Radiofrequency Ablation (Abstract 105) – In radiofrequency ablation (RFA), heat is delivered directly into the tumor via a probe that is inserted through the skin using CT and ultrasound imaging for guidance. From the tip of the needle, radiofrequency energy is transmitted into the targeted tissue, where it produces heat and kills the tumor. RFA is also a nonsurgical, localized treatment that spares healthy tissue without any systemic side effects.

Like cryoablation, radiofrequency ablation can be performed without affecting the patient’s overall health and most people can resume their usual activities in a few days.

This study showed that pain relief was achieved within a week for all of the 11 patients who underwent RFA. According to the visual analogue pain scale (VAS), patients’ pain was reduced by 2 or more points on a 10-point scale. The mean VAS score decreased dramatically from 6.4 to 0.7. No patients experienced local recurrent pain during the mean follow-up period of 5 months.

Osteoplasty (Abstract 36) – Osteoplasty treats bone pain by injecting medical-grade bone cement into the tumor. The cement gives off heat when mixed which kills the tumor, and then hardens to reinforce weakened bone that otherwise would be susceptible to fracture.

Tumors often eat away healthy bone, and in weight-bearing bones this technique can be particularly useful because it can prevent fracture. This is an established technique used to treat painful vertebral metastases or fractures in the spine from osteoporosis. Most recently, interventional radiologists have adapted this technique to other bones in the body.

Most frequently, this is an outpatient procedure performed using conscious sedation. The interventional radiologist inserts a needle through a small incision above the affected bone, directing it under fluoroscopy (continuous X-ray imaging) into the tumor. The physician then injects a medical-grade bone cement which hardens in about 15 minutes.

This study showed that osteoplasty is a safe and effective treatment for unremitting cancer pain and gives prompt and dramatic pain relief and return to function. The study presents a case series of patients treated with this technique at one hospital. Three men and two women were treated for malignant disease, and two women and one man for benign disease, for a total of eight patients. The treatment was successful in all eight patients, who experienced prompt and lasting pain relief. Additionally, there were no significant complications.

About Bone Cancer

Bones are the third most common location where cancer cells spread and metastasize. Bone metastases occur when cancer cells gain access to the blood stream, reach the bone marrow, begin to multiply and then grow new blood vessels to obtain oxygen and food — which in turn allows the cancer cells to grow.

Some bone metastases become painful because the tumor partially destroys bone, making the bone thin and weak. As the bones are replaced with tumor, nerve endings in and around the bone are continuously irritated and send pain signals to the brain.

If left untreated, bone metastases can eventually result in fracture with minimal activity—seriously affecting a patient’s quality of life. This is particularly true for long bones of the extremities where a fracture may render a limb nonfunctional. These patients may require surgical intervention to restore the function of their limbs. More commonly, metastases involve the ribs, pelvis, and spine. For the most part, the goal of treating bone tumors is not curative, but rather palliative by reducing pain, preventing additional bone destruction, preventing fracture, and improving function.

About Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology’s 30th Annual Scientific Meeting in New Orleans. Interventional radiologists are board-certified physicians who specialize in minimally invasive, targeted treatments performed using imaging for guidance to treat diseases nonsurgically through the blood vessels or through the skin. By combining diagnostic imaging expertise with advanced procedural skills, interventional radiologists perform minimally invasive treatments that have less risk, less pain, and less recovery time than open surgery. Interventional radiologists pioneered minimally invasive modern medicine with the invention of angioplasty and the catheter-

delivered stent, which were first used to treat peripheral arterial disease. More information can be found at www.SIRweb.org.

Interviews, medical illustrations and broadcast quality video footage are available. Abstracts can be found at www.SIRmeeting.org in the program section and click on scientific sessions.

###