

CRYOABLATION: Lung Metastases | ECLIPSE STUDY

Evaluating Cryoablation of Metastatic Lung Tumors in Patients - Safety and Efficacy. The ECLIPSE Trial—Interim Analysis at 1 Year

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The ECLIPSE Study: Efficacy of Cryoablation on Metastatic Lung Tumors with a 5-Year Follow-up

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Combined look at the ECLIPSE multicenter, prospective, single arm study over 5 years.

STUDY OBJECTIVE:

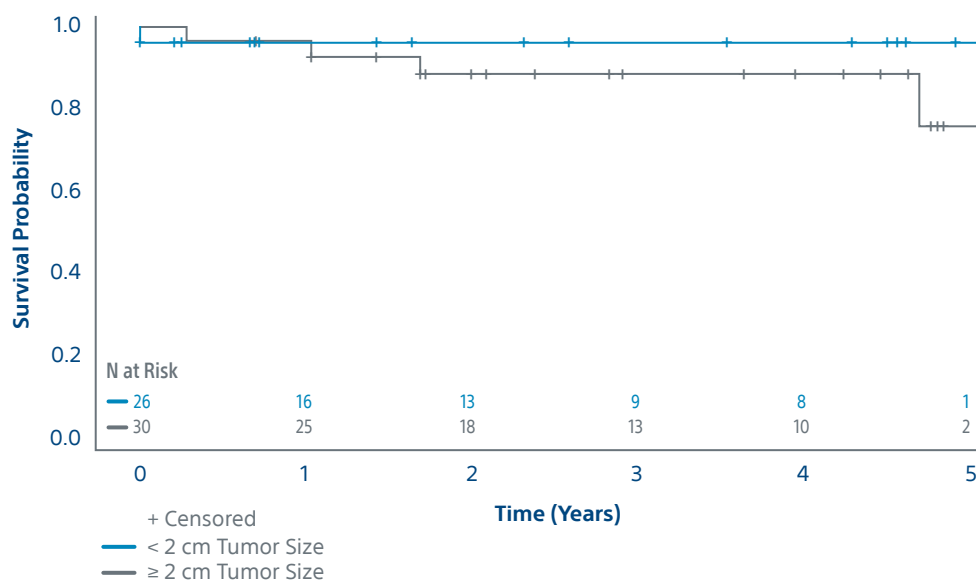
- Primary objective was to assess 5-year local control of CA in lung tumors of 3.5 cm or less in patients with pulmonary metastatic disease
- Secondary objectives to evaluate cancer-specific and overall survival, as well as, evaluate changes in quality of life (QoL) over a five-year period

KEY RESULTS:

Local Tumor Control Rates



Local Control by Lesion Size



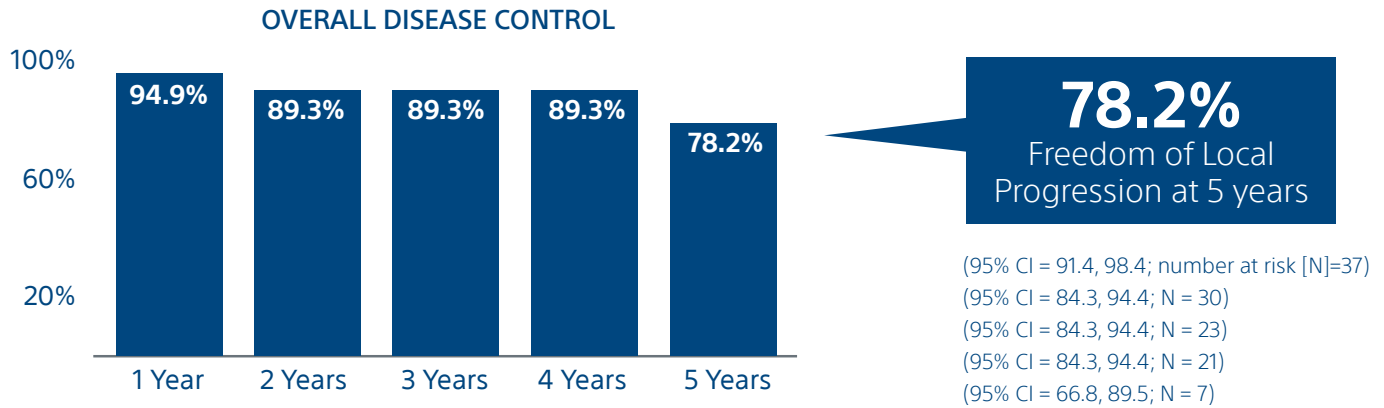
5-Year Local Control
88.9% Lesions < 2 cm
73.3% Lesions ≥ 2 cm

Local tumor control based on change from Month 3 of treated tumors (N = 56) by tumor size*

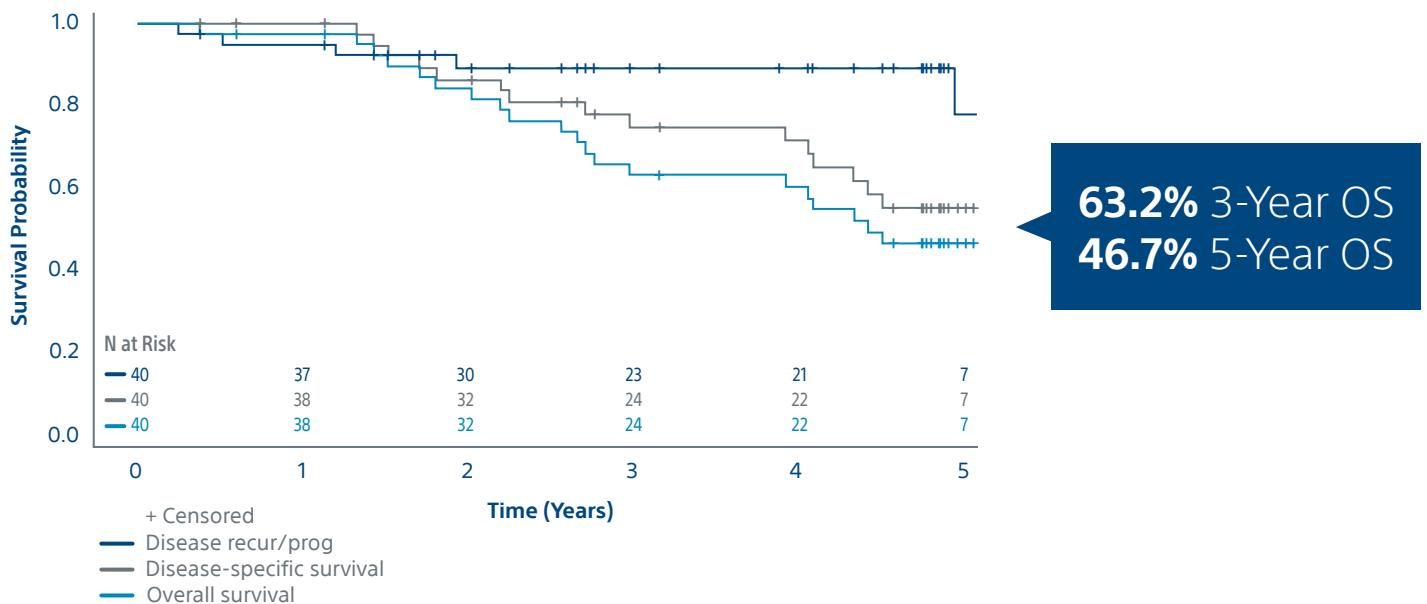
*Note: Four tumors were not included in analyses as 3-month imaging was not available at that time point.

Freedom from Local Progression

Patients free from local progression without additional locoregional treatment at the index lesion.



Survival Curves



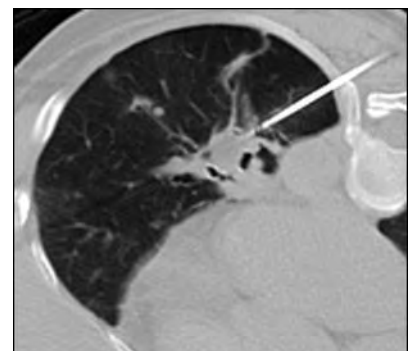
Disease Specific Survival

74.8%
3 Years

55.3%
5 Years

DEMOGRAPHICS

- Patients with 60 lung metastases were treated during 48 cryoablation procedures
- Inclusion Criteria: 1 to 5 metastases from extrapulmonary cancers, with a max diameter of 3.5 cm
- Patients were 62.6 ± 13.3 years old (26–83)
- The most common primary cancers were colon (40%), kidney (23%), and sarcomas (8%)



TREATMENT

- Cryoablation was performed under general anesthesia (67%) or conscious sedation (33%)
- Mean size of metastases was 1.4 ± 0.7 cm (0.3–3.4), and metastases were bilateral in 20% of patients
- Technical success for each treated tumor was defined as a zone of ground glass opacity, or visible ice encompassing the targeted tumor with at least a 5 mm circumferential ablative margin on CT at end of the cryoablation
- Cryoablation was performed applying a three-cycle freeze–thaw phase protocol
 - The times for each phase were recorded and varied as a function of the size of the tumor: targeted protocol–



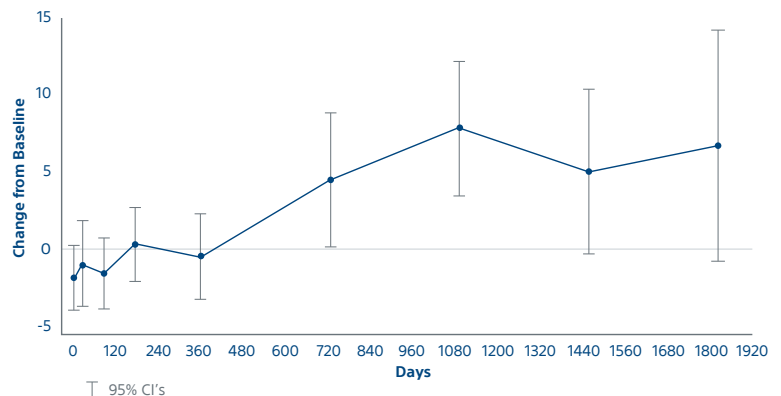
- Each procedure was monitored with non-contrast CT imaging at 3 to 5 minutes intervals to visualize the evolving ablation zone with the goal of achieving a circumferential margin beyond the tumor of 5 mm
- Immediate technical success was obtained in all 40 patients (100%) and 60 tumors (100%)

ADVERSE EVENTS

- One patient withdrew from study for treatment failure
- Three patients experienced pneumothorax (two Grade 2 and one Grade 3)
 - Grade 2 - prolonged hospitalization
 - Grade 3 - required hospitalization with chest tube insertion and vascular access complication and underwent thrombectomy, did well, and was subsequently discharged

QUALITY OF LIFE

QoL, as measured by Karnofsky Performance Score (KPS) improved over time, without statistical significance. While improvements were not considered statistically or clinically significant during early follow-up visits, some became clinically meaningful over time.



ECLIPSE STUDY CONCLUSION

Cryoablation is an effective means of local tumor control in patients with metastatic lung disease, with the majority of surviving patients maintaining local tumor control at the index tumor site over 5 years. Furthermore, cancer-specific survival and overall survival were greater after 5 years than for many other local treatment modalities, including surgical resection.

CRYOABLATION NEEDLES (IceSeed 1.5, IceSphere 1.5, IceSphere 1.5 CX, IceRod 1.5, IceRod 1.5 PLUS, IceRod 1.5 i-Thaw, IceRod 1.5 CX, IcePearl 2.1 CX and IceForce 2.1 CX) and ICEFX and VISUAL ICE CRYOABLATION SYSTEMS

INDICATIONS: The Galil Medical Cryoablation Needles and Systems are intended for cryoablative destruction of tissue during surgical procedures. The Cryoablation Needles, used with a Galil Medical Cryoablation System, are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. Galil Medical Cryoablation Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors and skin lesions) by the application of extremely cold temperatures. A full list of specific indications can be found in the respective Galil Medical Cryoablation System User Manuals. **CONTRAINDICATIONS:** There are no known contraindications specific to use of a Galil Medical Cryoablation Needle.

POTENTIAL ADVERSE EVENTS: There are no known adverse events related to the specific use of the Cryoablation Needles. There are, however, potential adverse events associated with any surgical procedure. Potential adverse events which may be associated with the use of cryoablation may be organ specific or general and may include, but are not limited to abscess, adjacent organ injury, allergic/anaphylactoid reaction, angina/coronary ischemia, arrhythmia, atelectasis, bladder neck contracture, bladder spasms, bleeding/hemorrhage, creation of false urethral passage, creatinine elevation, cystitis, diarrhea, death, delayed/non healing, disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), ecchymosis, edema/swelling, ejaculatory dysfunction, erectile dysfunction (organic impotence), fever, fistula, genitourinary perforation, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, impotence, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, organ failure, pain, pelvic pain, pelvic vein thrombosis, penile tingling/numbness, perirenal fluid collection, pleural effusion, pneumothorax, probe site paresthesia, prolonged chest tube drainage, prolonged intubation, pulmonary embolism, pulmonary insufficiency / failure, rectal pain, renal artery/renal vein injury, renal capsule fracture, renal failure, renal hemorrhage, renal infarct, renal obstruction, renal vein thrombosis, rectourethral fistula, scrotal edema, sepsis, skin burn/frostbite, stricture of the collection system or ureters, stroke, thrombosis/thrombus/embolism, transient ischemic attack, tumor seeding, UPJ obstruction/injury, urethral sloughing, urethral stricture, urinary fistula, urinary frequency/urgency, urinary incontinence, urinary leak, urinary renal leakage, urinary retention/oliguria, urinary tract infection, vagal reaction, voiding complication including irritative voiding symptoms, vomiting, wound complication, and wound infection. **PI-719210-AA**

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