

RELEASE IN PART B6

## Althera's First in Human Studies Press Release 11/7/11

### **Major Israeli Institution Selected to Lead Human Clinical Trials for Revolutionary Alpha Radiation Cancer Therapy.**

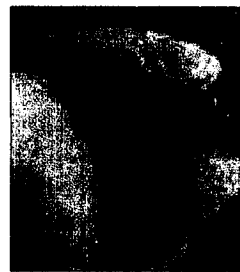
Althera Medical Ltd. announced today that it intends to perform a First-in-Human study for its revolutionary treatment of malignant tumors with alpha radiation at Israel's eminent Rabin Medical Institute. Professors Benjamin Corn, M.D., Chairman of Radiation Oncology at the Sourasky Medical Center and Althera's Chief Medical Officer, and Aron Popovtzer, M.D., Chief of the Head and Neck Tumor Service at Rabin's Beilinson Hospital will lead the study.

Althera's alpha radiation delivery system is expected to offer hope to patients suffering from head and neck, colon, pancreatic, sarcoma, brain, melanoma and lung cancer. Althera's Chairman, C. Leonard Gordon, a lawyer and entrepreneur with previous in-depth experience in successfully bringing medical devices through the FDA approval process and to market, believes that Althera's technology could be made available to these patients rapidly under the FDA's Compassionate Use policy.

Professor Michael J. Zelefsky, Chief of Memorial Sloan Kettering's Brachytherapy Service, said "the advantages of alpha over beta and gamma radiation are expected to be shown in these studies. Althera's unique method of alpha radiation delivery is expected to minimize side effects."

John Brown MD advises that preclinical studies at Tel Aviv University are "Proof of Principle" that DaRTS™ will work on tumors in the Althera's human clinical studies. Dr. Brown is currently Head of Global Strategic Drug Development & Alliances, Quintiles PLC. He has served as Global V.P. and in Experimental and Translational Medicine areas for SmithKlein Beecham. Dr. Brown has served as an advisor and a Director of Althera since 2007.

Althera's therapy delivers alpha radiation using tiny needles called DαRT™ (Diffusing Alpha-emitters Radiation Therapy) invented by Professor Itzhak Kelson of Tel Aviv University.

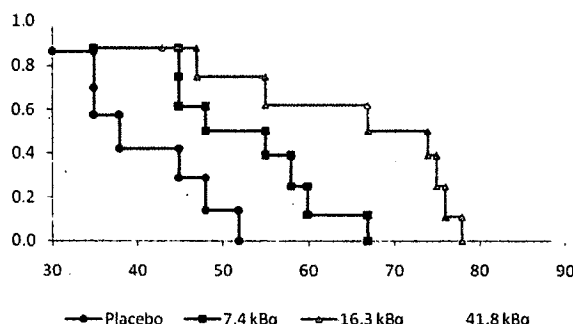
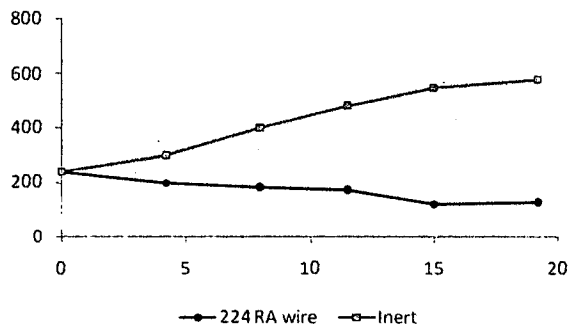


DαRT™

**CHARTS FROM ANIMAL STUDIES AT TEL AVIV UNIVERSITY LABORATORIES**

**Tumor Growth**

**Survival**



Dr. Steven Evans, CEO of Althera Medical, stated that "alpha radiation has been the 'holy grail' of radiation therapy for more than 50 years, but wasn't used because it couldn't be delivered. DaRTS™ solved this problem. After they are

injected into tumors and begin to generate alpha radiation that diffuses radiation throughout the tumor, killing cancer cells and shrinking or destroys the tumor.”

Althera is now moving to regulatory approval for human use on recurrent head & neck cancer. The National Cancer Institute estimates that \$3.1 billion is spent on head and neck cancer annually. In addition to head & neck cancer, Althera will move as soon as possible to treat recurrent head & neck, colon, pancreatic, sarcoma, brain and lung cancers. These are today's unmet needs that could be treated soon under the FDA Compassionate Use Policy that is typically approved for individual patients prior to a regular FDA approval.

The end point of the First-in-Human clinical study is safety, with secondary endpoints of tumor reduction and relief of pain. The study may require as few as 15 patients and is a prerequisite to larger FDA and European regulatory studies and Compassionate Use treatments.

Dr. Evans stated that DaRTS™ will be much less expensive and easier to administer than beta or gamma radiation. DaRTS™ do not require heavy equipment, specially shielded rooms or lead vests, and the entire dosage can be delivered in a single session. Also, Alpha radiation breaks the double strand of DNA of the cancer cells, hindering cancer cells from repairing themselves and thereby reducing the possibility of radiation-resistance in tumors. Radiation, he noted, is a big market that is currently used in about 50% of all tumor therapies.

The First-in-Human Study is expected to start in a few months if not delayed by financing which has been difficult in the face of the recession. It is expected that financing will be successful now that there is proof of principal that DaRTS™ do work on human tumors and are so close to human clinical studies.

Althera Medical is an Israeli Company with its headquarters co-located in New York City's Harlem and in Tel Aviv. Its Advisory Board contains eminent Interventional Radiologists, Brachytherapists and Radiation Oncologists at Memorial Sloan Kettering, Johns Hopkins, and at major hospitals in Israel and Europe.

**Questions should be addressed to C. Leonard Gordon at**

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B6

## **Medical Advisory Board**

**Michael Zelefsky, M.D.:**

Chief, Brachytherapy, Memorial Sloan Kettering Cancer Center

**David Sidransky, M.D.:**

Director, Head and Neck Cancer Research, Johns Hopkins University Hospital

**Marco Zaider, Ph.D.:**

Head of Brachytherapy Physics, Memorial Sloan Kettering Cancer Center

**Jean Claude Horiot, M.D., Ph.D.:**

Director of the Cancer Institute G.F. Leclerc, Dijon, France

**Abraham Kuten, M.D.:**

Director Radiation and Medical Oncology, Rambam Medical Center, Israel

**Stephen Solomon, M.D.:**

Chief, Interventional Radiology, Memorial Sloan Kettering Cancer Center

## **Peer Reviewed Scientific Publications**

*The treatment of solid tumors by alpha emitters released from (224)Ra-loaded sources-internal dosimetry analysis. Arazi L, Cooks T, Schmidt M, Keisari Y, Kelson  
Phys Med Biol. 2010 Feb 21;55(4):1203-18*

*Local control of lung derived tumors by diffusing alpha-emitting atoms released from intratumoral wires loaded with radium-224. Cooks T, Schmidt M, Bittan H, Lazarov E, Arazi L, Kelson I, Keisari Y.*

*Int J Radiat Oncol Biol Phys. 2009 Jul 1;74(3):966-73.*

*Interstitial wires releasing diffusing alpha emitters combined with chemotherapy improved local tumor control and survival in squamous cell carcinoma-bearing mice. Cooks T, Arazi L, Efrati M, Schmidt M, Marshak G, Kelson I, Keisari Y.*  
*Cancer. 2009 Apr 15;115(8):1791-801.*

*Growth retardation and destruction of experimental squamous cell carcinoma by interstitial radioactive wires releasing diffusing alpha-emitting atoms. Cooks T, Arazi L, Schmidt M, Marshak G, Kelson I, Keisari Y.*

*Int J Cancer. 2008 Apr 1;122(7):1657-64.*

*Treatment of solid tumors by interstitial release of recoiling short-lived alpha emitters. Arazi L, Cooks T, Schmidt M, Keisari Y, Kelson I.*

*Phys Med Biol. 2007 Aug 21;52(16):5025-42.*