

Presentations Feature CPSI's FrostBite GI Cancer Cryoablation Platform

Studies focused on the FrostBite device platform and cancer response to cryoablation highlight the potential use of this next generation technology for the treatment of pancreatic and esophageal cancer.

August 3, 2016 - Owego, NY – The need for the development of new devices and strategies to treat cancer was front and center at this year's annual meeting of the Society for Cryobiology held in Ottawa, Canada in the session "Cool Developments in Cryomedicine". This 2 part, 4-hour session featured 9 presentations focused on new developments in the use of cryo for disease treatment. As part of the session, CPSI scientists presented three studies focusing on molecular studies and device development in the areas of prostate (John M. Baust, Ph.D., CPSI President), pancreatic (Anthony Robilotto, MS., CPSI Engineer) and esophageal cancer (Kristi Snyder, Ph.D., Principal Scientist). Central to these studies was the incorporation of several of CPSI's new device technologies including the PSN cryoablation device, *FrostBite* cryoablation catheter and *EsoAblate* cryoprobe. The *FrostBite* and *EsoAblate* cryoprobes are under development for the minimally invasive endoscopic based treatment of pancreatic and esophageal cancer, among other gastrointestinal cancers. The studies included discussion of cancer cell response to freezing, device design and characterization analysis as well as data from a series of studies conducted using tissue engineered pancreas and esophageal cancer models. The presentations also included results from preliminary *in vivo* studies conducted in conjunction with collaborators at Johns Hopkins Medical which demonstrated the successful translation of CPSI's engineering and life science development into functional systems capable of delivering of an ultra-cold, highly lethal insult (ablative dose) within a matter of minutes.

Discussing the presentations, Dr. Baust stated "Our team has been involved in the field of cryoablation for years on both the cancer biology and device development fronts. This has allowed us to integrate cancer biology and cryogenic engineering to develop a better suite of surgical tools to destroy cancer. In the area of GI cancers, cryoablation has been shown to be very effective; however, technological limitations have limited its use. The *FrostBite* and *EsoAblate* cryocatheters aim to overcome this, providing physicians an advanced tool to combat these pervasive and highly lethal diseases." Mr. Robilotto continued "we have been studying the molecular response of cancer to freezing and other treatments for years. Through these efforts we have identified a number of biological phenomena that we were able to leverage in the development of the *FrostBite* platform. This will enable *FrostBite* to provide for more targeted, effective and rapid treatment of pancreatic and esophageal cancer."

The potential impact of the technology is tremendous given the very low five year survival rates for pancreatic (<5%) and esophageal cancer (<15%). This translated to >300,000 and ~400,000 deaths annually worldwide from pancreatic and esophageal cancer, respectively. Estimates suggest that ~45% of these individuals could be treated with cryo, representing a current market potential of >\$650 million. Speaking about the technology, Dr. P. Jay Pasricha (Professor of Medicine and Neurosciences, Division of Gastroenterology, Johns Hopkins School of Medicine)

stated “We are very encouraged by the results we have obtained so far with the *FrostBite* EUS-cryocatheter platform. The ability to target and freeze tissues *in situ* under endoscopic ultrasound guidance will provide for a more precise and minimally invasive strategy to treat cancer. In looking at the big picture, *FrostBite* has the potential to provide for a revolutionary approach to treating pancreatic cancer as well as other gastrointestinal diseases including esophageal, stomach and colorectal cancer. We are looking forward to continuing to work with the CPSI team to bring this technology to the clinic.” When asked to comment on the potential impact of the technology Dr. Snyder stated, “the ability to quickly and controllably deliver an ultra-cold, highly powerful cryogenic insult to tissue targets in a minimally invasive procedure has the potential to change how we treat many diseases. Our belief is that this technology will provide cutting edge treatment options for the 10’s of millions of individuals in the US and worldwide battling cancer annually.”

With the development of this revolutionary technology, CPSI is now poised to embark on technology commercialization. Baust stated “To succeed in today’s regulatory landscape companies must focus. To this end, we are focusing on the GI area via a partnership with GI Cryo, Inc. for which we are now actively seeking partners to commercialize this platform.”

More information on the *FrostBite* cryoablation platform can be found on CPSI’s website at www.CPSIBiotech.com.

About CPSI Biotech - CPSI Biotech, a private, integrative bio/medtech greenhouse company, develops and designs life science research products and cryo-medical devices for applications in cancer, cardiovascular disease treatments and cell therapy bioprocessing. Ongoing R&D and business development activities continue to produce innovative technologies, devices and intellectual property for commercialization, licensing or sales in support of diverse clinical and research applications. By leveraging the innovation, flexibility and R&D strengths of CPSI in combination with the development, commercialization, manufacturing and clinical expertise of partnering organizations, rapid and efficient product development is attainable.

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