

CLINICAL TRANSLATION OF A NOVEL CANCER NANOTHERAPEUTIC AGENT- BENCH TO BEDSIDE FROM A SMALL COMPANY PRESPECTIVE

Nanoparticles of gold are inherently multifunctional in their diagnostic and therapeutic capabilities. ^{198}Au , provides a desirable beta energy emission and half-life for effective destruction of tumor cells/tissue (max = 0.96 MeV; half-life of 2.7 days). The range of the ^{198}Au β -particle is sufficiently long to provide cross-fire effects of radiation dose delivered to cells within the prostate gland and short enough to minimize significant radiation dose to critical tissues near the periphery of the capsule. In order to capitalize on the well known tumor affinity of gold nanoparticles to tumor vasculature, Nanoparticle Biochem Inc (NBI), has developed proprietary technology that allows efficient conversion of radioactive gold-198 to its corresponding therapeutic nanoparticles with subsequent stabilization via conjugation with Gum Arabic protein matrix. As part of the SBIR Phase I effort, Nanoparticle Biochem Inc (NBI) has successfully completed detailed therapeutic efficacy studies in prostate tumor bearing mice and toxicity studies of the non radioactive surrogate of NBI 29 in pigs. Intratumoral injection of NBI's proprietary gold nanoparticle based injectable agent: $^{198}\text{AuNP-GA}$ (NBI-29), has unequivocally demonstrated that over 90% of the injected dose remains in the tumor over a 24 hour (and longer) time period and that the agent effectively shrinks and suppresses the growth of prostate tumors in mice to such levels that are not commonly observed with any chemo or radiotherapeutic agent (Katti, Kannan and others in *Nanomedicine* Volume 6, Issue 2, Pages 201-209 April 2010; featured article on the cover page in April 2010 issue). No toxic side effects were noted for over 40 days of studies in mice and for over 120 days investigation in pigs (using the non radioactive surrogate). Limited Phase I clinical trial studies in client owned dogs with naturally occurring prostate tumors, which mimic androgen independent prostate tumors in men, have already provided unequivocal evidence on the realistic clinical potential of NBI 29 as a new generation nanotherapeutic agent for treating inoperable solid tumors. In order to clinically translate the therapeutic potential of NBI 29 for treating prostate tumor human patients, Nanoparticle Biochem Inc has recently entered into a joint product development effort with Shasun Pharmaceutical Company of India. Shasun-NBI LLC will focus product development efforts aimed at completion of toxicity/therapeutic efficacy in dogs to allow filing of an IND application with the US FDA to commence Phase I clinical trials in human prostate cancer patients. Product development efforts, incorporating platform nanotechnology of Shasun-NBI LLC, as outlined above, will be carried out in collaboration with internationally reputed group of interdisciplinary scientists, consultants and cancer therapy experts within the University of Missouri and chosen from other locations with expertise in (i) therapeutic isotope production; (ii) nanotechnology as it relates to applications in nanomedicine; (ii) tumor biology (iii) radiation/clinical and surgical oncology; (iii) medical physics and dosimetry; (iv) veterinarians with strong comparative oncology track record; and (v) conducting Phase I-III clinical trials leading to final approval by the US FDA

Implications for prospective investors in terms of the potential of Shasun-NBI LLC's 'Platform Nanotechnology' for the development of sophisticated therapy agents for treating hepatocellular and pancreatic cancers will be presented.

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