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### **Human sperm generated nanosomes in vivo A new challenge in preventative therapy for prostate cancer**

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Using the compound Styrene maleic anhydride (SMA) as a model of a drug, a novel approach for sustained endogenous formed liposome encapsulated drug delivery to the prostate gland has been designed. Intra vas deferens depot of a combination of high molecular weight SMA (SMAh, the drug) and low molecular weight SMA (SMAI) is formed by one time injection.

The SMAh breaks down sperm membrane to provide a continuous supply of phospholipids macrocomplexes – as mesosomes – from the sperm. The SMAI forms cleavage centers causing slow breakaway of nanoSMAh fragments, as nanoliposomes – nanosomes. Vas peristaltic activity and fluidic pressure provide the mechanical forces bringing reactants together leading to natural encapsulation of nano particles of SMAh within phospholipids shells giving a continuous supply of sperm-derived nanoliposomes. A dimethyl sulfoxide (DMSO) constituent of the depot leads to the sulfur attachment on the new generated liposomes, accounting of the nanosomes passage through the vas deferens – prostate barrier by a prostate tissue sulfur affinity mechanism.

The BioConcept has been tested by implantation of the SMA in the rat vas deferens: formation of nanoliposomes in vivo; actual encapsulation of SMA within the liposome; the overall Drug Encapsulation Efficiency; the presence of liposomes in the vas deferens fluid and transfer to the prostate have been confirmed by Transmission Electron Microscope (TEM) examination and Fluorescence Microscopy following Nile Red staining of vas fluid and prostate tissue. This full chemical process has been patented Internationally (Patent granted EP 2268290).

The First Designed Drugs – RISUG and RISUG Adv – have been applied on large scale as Reversible Contraceptive Method in Males in India, under the aegis of the Ministry of Health and the Society of Andrology of India – SAI, and are currently tested in some European Countries on an official European clinical trial, directed by Prof. Giuseppe Tritto.

With increasing longevity greater numbers of males are coming into the age group of high incidence of BPH and of prostate cancer. Therefore preventive solutions are of major interest. The potentiality of linking drugs as finasteride to the nanoliposomal complex has been explored, due to the unique capability to generate Nanoliposomes inside the vas deferens with the specific property to cross through the vas deferens-prostate barrier: a continual formation of drug encapsulated nanosome is obtained. This innovative solution opens new possibilities in preventative and regenerative medicine in the major pathologies of the prostate and in the management of early stages and localized prostate cancer.

**Keywords:** Styrene maleic anhydride, molecular weight, phospholipids, transport, vas deferens, prostate, liposome nanosome, sperm, electron microscopy, fluorescence microscopy and finasteride.

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