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Bridging BASIC BIO-NANO-SCIENCE and CLINICAL TRANSLATION

NANOMEDICINE NANOBIOTECHNOLOGY

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My 27 Years of Failure (Trying to Cure Lung and Liver Metastases)

Dr. Mauro Ferrari

University of St Thomas, Minnesota, United States of America

Nanomedicine has been a great success, in research laboratories, and in the clinic, since its emergence in medicine about 25 years ago. Yet, it has not been able to yield a general cure for metastatic disease to lungs and liver - which unfortunately are responsible for the vast majority of cancer deaths. nenomedicine is not alone in this "failure" - all other approaches have similarly failed, to date, including chemotherapy, molecularly targeted biotherapeutics, and immunotherapy. In my talk, I will give an overview of my long and rather colorful list of personal failures in attempting to do just that: To cure visceral metastases, regardless of their primary cancer site of origin. Along the way, I found myself in the early, formative stages of nanomedicine - and we have continued to share the journey until now. Post-nanomedicine I also developed a number of different approaches, which employed nanotechnology as one of the components of the attempted solutions. This gave rise to other fields, such as multi-stage vectors (MSV), transport oncophysics (TOP), and injectable nanoparticle generators (iNPG). A combination of these is now giving me new hope that a cure for metastatic disease to lung and liver for many may actually be reachable, soon. We have developed a new drug, regulatory codename ML-016, (scientific name iNPG-pDox), which has shown unprecedented curative results in preclinical models, and now we are taking it to the clinic. We have developed and scaled up good manufacturing techniques, build a specialized facility, progressed through toxicity studies with exemplary results, and had independent verification of of efficacy results. We established a company (BrYet, LLC) and secured the portfolio of issued and pending patents supporting ML-016. Independent clinical trials on triple-negative breast cancer with visceral metastases are scheduled to start in June at Houston Methodist hospital, with support from the Department of Defense of the USA, under the clinical leadership of Dr Jenny Chang. BrYet is looking at starting its all-comer visceral metastases Phase I/Ib later in 2020. in this talk, I will focus on recent scientific developments of importance for for ML-016, and namely novel validations for its postulated, transport-based MOA (primary authors: Shreya Goel, Haifa Shen); and new discoveries on the modalities of uptake of particulate drugs (more in general than ML-016) by the liver and other biological barriers (primary author: Sara Nizzero).

Looking forward to discussing it all with you!

My most cordial regards.

Mauro

www.premc.org/iconan
iconan2019@premc.org