NanoView BIOSCIENCES

MSC EXOSOMES, MESENCHYMAL STEM CELL (MSC) DERIVED EXOSOMES · ARTICLE

Characterization of Mesenchymal Stem Cell (MSC) Derived Exosomes

Applications of cell therapies in humans have been an area of tremendous research efforts and clinical applications are becoming commonplace. In these therapies whole living cells are used to treat or cure a disease, their mechanisms of action are highly complex and involve all of the

released by the MSCs into the extracellular space. The exosomes and other extracellular vesicles are 30-1000 nm closed lipid structures which contain a variety of important nucleic acid, protein, and enzyme factors that are released to facilitate intracellular communication. Because these exosomes and extracellular vesicles carry the signaling factors which elicit changes in recipient cells, their application in place of whole cell therapy to decrease immune reaction in the recipient is an area of active investigation [1,2,3].

Recent studies have shown a broad range of potential therapeutic uses for Mesenchymal Stem Cell (MSC) derived vesicles for the

treatment of numerous conditions [4,5], further on their potential for engineered delivery of cytotoxic or modulating molecules [6,7]. Despite all of this promise there are still many years of research before we can expect to see exosome therapies in regular clinical use. Recently, the FDA has released a warning regarding exosome products being used in humans for therapies through stem cell clinics, their release reminds readers that there are currently no approved exosome products on the market to treat any condition [8]. Additionally, any exosome or other

an Investigational New Drug filing (IND). We can compare the relative requirements for selling of therapeutics under 351 and the currently inappropriately used 361 (Human Cell Tissue/Product) designation in the table below:

	351 Products	361 Products
Product Class	Biologic	HCT/P
FDA Approval	Required for marketing	Not Required
Labeling Claims	Indicated for specific use	No clinical, homologous
Potency/Bioactivity	Assured	Not Tested
Purity	Assured	Not Tested
Design	Novel	Commodity
Barrier to Entry	High	Low
Clinical Data Requirement	Randomized Controlled (2 Confirmatory)	None

There are at present many producers of stem cell exosomes, some of whom are marketing mislabeled products to consumers [8]. There is also little overarching consensus on how to measure many properties of these exosome / extracellular vesicle formulations. With an eye toward the regulatory requirements of the FDA for documentation and control the question becomes… What is appropriate for the characterization of an exosome drug?

recommends the measurement of surface proteins (at least 3), the apparent nanoparticle size distribution of the isolated exosomes and other extracellular vesicles, confirmation of membrane integrity (closed particles), and some form of activity assay while offering various choices of techniques for each type of measurement [9]. Researchers at present typically employ western blot for protein detection and various particle counting tools for determination of the nanoparticle size distribution, leaving the user with disconnected results and assumptions about the quantitation and stoichiometry of their supposed active ingredients and delivery vehicle. Is this limited resolution suitable for the determination of physical properties associated with a cutting-edge drug substance? Perhaps it is when it's the only tool available, but now using our ExoView platform investigators can bridge this disconnect by directly measuring the protein display of multiple markers, and nanoparticle size of at the discrete single exosome and other extracellular vesicle level. This type of measurement allows the investigator to define relative levels of different subpopulations of extracellular vesicles which may be present in a complex mixture,

mode of analysis that lets investigators truly define its size and constituent composition. The ExoView tests can then be used to ensure quality and consistency in clinical investigations and future manufacturing. To learn more visit our website or download our detailed e-book on exosome characterization.

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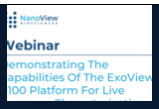

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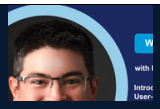

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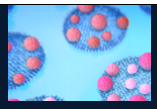

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