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From Mesenchymal Stem Cells to cell products: secretome pharmaceuticalization as a safe and effective biological medicinal product

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Mesenchymal stem cells (MSCs) exert their therapeutic action through the secretion of their secretome, made of free-soluble factors (cytokines, chemokines and growth factors) and insoluble nano/micro-structured extracellular vesicles (EVs). MSC-secretome efficacy has been widely established for many diseases in numerous preclinical models, and the advantages of a-cellular therapies, as regards safety and technological issues, are evident [1]. However, strategies must be designed to translate secretome research successfully and to develop safe and efficacious therapies. In this regard, for the first time, we proposed the secretome “pharmaceuticalization” into a high quality, safe and effective medicinal product. A validated, scalable and Good Manufacturing Practice-compliant preparation process has been defined: MSC-secretome is purified from culture supernatants by ultrafiltration, added with cryoprotectant and lyophilized, obtaining lyo-secretome, a freeze-dried and “ready-off-the-shelf” powder containing EVs and proteins [2]. Such “ready-to-use” product allows physicians to exploit, effortlessly, all the therapeutic potential of MSC-secretome in the field of immunomodulation [3], pulmonary diseases [4], skin wounds [5], and musculoskeletal disorders [2]. Interestingly, recently, our pharmaceuticalization of MSC-secretome into freeze-dried and stable powder products, exploiting large-scale and GMP preparation procedures, appeared as a well-suited approach for the treatment of patients with COVID-19 pneumonia, especially for the ones in critically severe condition [6].

References

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