Title: MNC secretome: from discovery to product science and patient: from ignorance to clinical trial

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Hendrik Jan L. Ankersmit was born in Durban, South Africa, and grew up in Johannesburg, South Africa, and Klagenfurt, Austria. He studied medicine and philosophy, earning his doctorate in 1994. He then performed postdoctoral research at Columbia University (1996–1997), and underwent specialized training in general and thoracic surgery. In 2004, he completed his habilitation. In 1999, he founded the “Applied Immunology” working group at the Medical University of Vienna. Ankersmit is working as consultant at the Thoracic Surgery Department at the Medical University of Vienna.

Ankersmit’s notable scientific contributions include providing the first descriptions of leucocyte apoptosis and programmed cell death in vivo in patients supported by ventricular assist devices (VADs), in patients with sepsis, in patients undergoing dialysis treatment, and in heart transplant patients diagnosed with transplant-associated vasculopathy (1999–2003). He was the first to describe an alpha-Gal-specific humoral immune response in recipients of biological prostheses (2005–2009), and provided the first description of CD32-mediated platelet aggregation induced by IVIG and ATG in vitro (2004, 2008). He was the first to identify alveolar pneumo-epithelial cells as the main producers of soluble ST2 (2010), and the first to describe the post-CABG immune status as immunological anergy (2005–2016). Ankersmit first identified an autoimmune state in patients diagnosed with chronic obstructive pulmonary disease (COPD) (2013–14), and performed serum biomarker research in patients with COPD and lung carcinoma (2009–2012) as well as the first prospective study to investigate air trapping/emphysema in heavy smokers with normal lung function (2013). In contrast to all prior stem cell literature, Ankersmit demonstrated that apoptotic white blood cells (peripheral blood mononuclear cells; PBMCs) and their secretory product prevented experimental myocardial infarction (2009). Based on these datasets, APOSECTM was patented in 2008. Over the following years, it was demonstrated that this PBMC-derived “cell-free biological” substance prevented inflammatory damage in multiple indications, including acute myocardial infarction, myocarditis, stroke, spinal cord injury, and wounding (2011–2018). In 2017, APOSECTM was tested for the first time in a PHASE I human trial.

Abstract
For almost two decades, cell-based therapies have been tested in modern regenerative medicine to either replace or regenerate human cells, tissues, or organs. The cell secretome includes a variety of proteins, lipids, microRNAs, and extracellular vesicles, such as exosomes and microparticles. The stem cell secretome has most commonly been investigated in pre-clinical settings. However, a growing body of evidence indicates that other cell types, such as peripheral blood mononuclear cells (PBMCs), are capable of releasing significant amounts of biologically active paracrine factors that exert beneficial regenerative effects. The apoptotic PBMC secretome has been successfully used pre-clinically for the treatment of acute myocardial infarction, chronic heart failure, spinal cord injury, stroke, and wound healing. In this review we describe the benefits of choosing PBMCs instead of stem cells in regenerative medicine and characterize the factors released from apoptotic PBMCs. This presentation will mirror the daily life experience of a translational scientist to develop a drug compound according to the ICH criteria. Such work includes the design of stability studies, comparability studies; retain samples, validated potency assays, the selection of a clinical research organization (CRO) and the design of a clinical trial in one clinical indication. This should allow the audience to envision what efforts it takes to translate the results of basic science, from the bench, to the patient.

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