

Applications of Advanced Therapy Medicinal Products in Oral Medicine

A.A. Bakopoulou*

Department of Prosthodontics, School of Dentistry, Faculty of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, GR-54124, Greece

Regenerative Medicine/Dentistry offers innovative approaches to restore damaged or lost tissues, based on the principles of tissue engineering (TE). Although research on advanced therapy medicinal products (ATMPs) has been very active in recent years, the number of licensed products remains surprisingly low and restricted to treatment of lethal or highly debilitating incurable diseases. Competent authorities worldwide have focused in developing regulatory pathways to accelerate treatments of unmet patient needs. Yet, the status remains still in early development, while several scientific, regulatory and cost-effectiveness issues, impose considerable hurdles to achieve marketing authorization, technology adoption and patient accessibility. In the context of this global landscape, Regenerative Dentistry, although achieving breakthrough innovations during the past years in TE of several dental and oral tissues in pre-clinical models, has hardly harnessed research progress to integrate innovative regenerative treatments into clinical practice. This presentation will disseminate our Institutional experience on the development of TE constructs tailored for application as ATMPs for oral tissue regeneration. It will also provide a brief overview of current clinical, regulatory and commercial status of cell-based therapies and will discuss the main hurdles to overcome to foster wider application in Regenerative Dentistry.

References

Bakopoulou A. Prospects of Advanced Therapy Medicinal Products-Based Therapies in Regenerative Dentistry: Current Status, Comparison with Global Trends in Medicine, and Future Perspectives. *J Endod.* 2020 Sep;46(9S):S175-S188. doi: 10.1016/j.joen.2020.06.026.

* abakopoulou@dent.auth.gr