

NEW
PHARMACEUTICALS
IN SKIN REGENERATION
MEDICINE

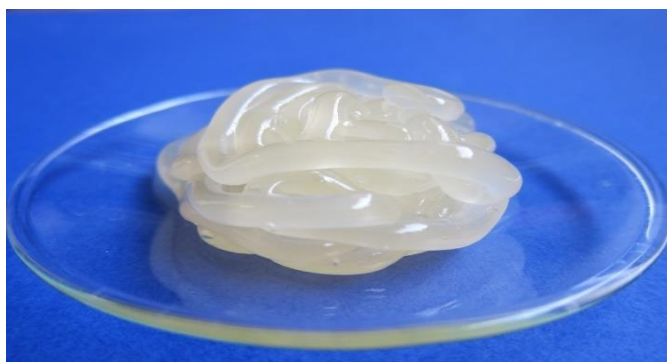


Technology

Skin is the largest organ of human body protecting it against physical, chemical and biological factors (viruses, bacteria, fungi). Its ability for regeneration/repair is essential to keeping full homeostasis of the body and provide protection against external factors. The process of skin repair and its regeneration depends on many types of cells such as stem cells or differentiated cells (e.g. keratinocytes, fibroblasts), as well as on growth factors, cytokines and extracellular matrix. The natural response of skin for injury is among the others activation of fibroblasts and starting of wound healing process. Fibroblasts are capable of quick filling large skin losses comparing to keratinocytes responsible for epidermal creation process. The proposed innovative pharmaceuticals can find many applications in various segments of regenerative medicine: orthopedics and musculoskeletal diseases, dermatology, cardiology, diabetology, neurology, radiology or oncology.

Their functioning is based on application of the following three technologies:

1. New application of the epigenetic regenerative therapy in mammalian body, consisting on administering of pharmaceutical composition comprising zebularine, its pharmaceutically acceptable salt, at least one pharmaceutically acceptable carrier, diluent and retinoic acid, retinoic acid metabolites and their pharmaceutically acceptable salts. The described composition is applied to stimulate the regeneration or healing of wounds induced by: mechanical, chemical, thermal, radiation injuries or surgical operations or other pathological conditions. The innovative substance used as therapeutic agent shows hypomethylating effect and activates genes of pluripotency and neurogenesis. After administration of its therapeutically effective dose, healing of chronic and non-healing wounds, pressure ulcers and wounds is occurred, being a result of diabetic or peripheral arterial disease complication. Next the regeneration of complex tissues including: neurons, blood vessels, muscles, cartilage, sweat glands, skin and epidermis, hair and hair follicles is followed.



Technology cont.

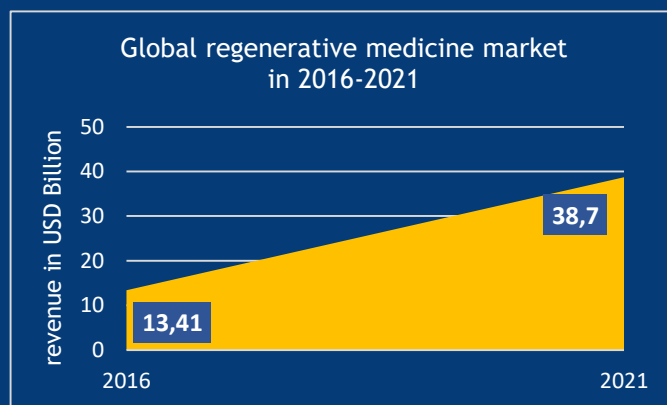
2. Application of novel composition comprising the IM peptide (i.e. hydrophilic hexapeptide of RDKVYR sequence, being a fragment 32-37 of thymobitin hormone produced by thymus) in order to stimulate the regeneration of complex tissue or healing wounds induced by: mechanical, chemical, thermal, radiation, surgical and other pathological conditions. New pharmaceutical composition comprises of IM peptide at appropriate concentration and/or its pharmaceutically acceptable salt. The research carried out by scientists under the REGENNOVA project proved that the substance described above significantly accelerates skin regeneration process. In addition, through the reconstruction of epidermis and dermis IM peptide inhibits a differentiation of keratinocytes, activated after a skin injury. Innovative composition can be applied in the form of ointment, cream, spray, injection or tablet. The element of proposed new technology is also a kit for stimulating the regeneration of complex tissue or wound healing, containing the above-described substance.

3. Method of producing and applying to the mammalian skin regeneration new RADA peptide structures comprising of self-assembled peptide hydrogels only. Process of creating new substances is carried out in stages. The new peptide structures have three characteristic fragments of amino acid sequences. One of them has innovative use of fragment specific for elastase (an enzyme involved in the remodelling of damaged skin), which after enzymatic cutting releases to the environment biologically active material, accelerating wound healing and skin reconstruction. In addition application of the material does not cause risk of allergic reaction or transmission of infectious disease. Innovative substances can be used for regeneration of complex tissue and treatment of wounds caused by mechanical, chemical, thermal, radiation, surgical and other pathological conditions.

Market

The number of patients suffering from poorly healing wounds and related skin changes reaches 100,000 in Poland. In the case of the US and the European Union this number exceed 3 and 6 million patients accordingly. Factors causing the prevalence of non-healing wounds are civilization diseases, e.g. diabetes, obesity, progressive aging of the population and age-related decline in the regenerative capacity of the body. The market for the proposed inventions is the regenerative medicine market, which can be divided into segments based on:

product type, type of therapy, type of application and geographical coverage. According to the report of Markets and Markets company, "Regenerative Medicine Market by Therapy (Cell Therapy, Tissue Engineering, Immunotherapy, Gene Therapy), Product (Cell-Based, Acellular), Applications (Orthopedic and Musculoskeletal Disorders, Dermatology, Oncology, Cardiology) - Forecast to 2021 "until 2021, revenues from this market is expected to increase from USD 13,41 billion in 2016 to USD 38,70 billion in 2021. The estimated CAGR for the period 2016-2021 will amount to 23,6%. Main factors of the market development and growth in revenue will be: government and private funds, the growing level of occurrence of chronic and genetic diseases, increase in global expenditure on health care, as well as aging of societies.



source: MarketsandMarkets Report, 2017

Commercialization opportunities



- ➔ Licensing relationship
- ➔ Partnership for further studies and commercialisation
- ➔ Transfer of ownership
- ➔ Spin-off

IP Status



The invention was submitted for patenting according to Polish P.425351, P.425597, P.423672 and international: EP18000264, PCT/PL2018/000027

Implementation progress



TRL 4
Technology validated in laboratory conditions

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