CELLULAR THERAPY MARKET IN BELARUS

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Why “cellular therapy”? 

XXI century in the time of battle with noninfectious (chronic) diseases: cancer, cardiovascular and lung diseases, diabetes, orthopedic pathology, etc.

Cellular therapy gives new opportunity for treatment most of these diseases when other possibilities became limited.
Expected growth of world regenerative medicine market for particular biotechnological products.
ClinicalTrials.gov  (17.04.2017)

Stem cell therapy
5443 studies

T-cell therapy
7270 studies

Dendritic cell therapy
662 studies

LAK cell + CIK cell therapy
13 + 90 studies

Cellular therapy
(35 825 studies, 20.6%)

Therapy
173 811 studies

immunotherapies:

iPC therapy
149 studies

Stem cell therapy
5443 studies

Endothelial cell therapy
1116 studies

Epithelial cell therapy
7116 studies

CART cell therapy
229 studies

Embryonic SC therapy
42 studies

MSC
4183 studies

HSC
3378 studies

auto MSC
220 studies

allo MSC
161 studies

Umbilical cord blood therapy
550 studies

Monoclonal antibody therapy – 4942 studies

Gene therapy – 5107 studies
Cellular therapy in Republic of Belarus: preliminary step

- Bone marrow transplantation program started in 1996.
- Occasionally autologous activated NK cells were prepared and administrated to patients with cancer.
Cellular therapy in Republic of Belarus: first step

In was started in 2006, when Ministry of Health announced first competition of research projects for development of methods of cellular therapy for most important human diseases.
Cellular therapy in Republic of Belarus: second step

Up to 2010 unified methodology to manufacture biomedical cellular products based on autologous mesenchymal stem cells was elaborated in 6 laboratories of cellular therapies in Minsk.

In 2012-2013 three laboratories have got accreditation for manufacture and release of biomedical cellular products for clinical use.
Cellular therapy in Republic of Belarus: third step

- The law of the Republic of Belarus “On Public Health” was added with Article 18-3 and it was introduced for work on June 16, 2014 by Act 164-Z.
- Article 18-3 regulates implementation of cellular products for medical use in Belarus.
- “Biomedical cellular products” were indicated as material for transplantation, based on human cells except of embryonic, fetal, hematopoietic and gene-modified human cells.
Cell type, using for cellular therapy in Belarus

- Mesenchymal stem cells (MSCs) from adipose tissue.
- Tissue-specific MSC-derived progenitor cells.
- Bone marrow-derived MSCs.
- Dendritic cells.
- Cytokine-inducing killer cells.
- Bone marrow-derived hematopoietic stem cells.
- Umbilical cord blood cells.
- Parathyrocytes.
- Pancreatic β–cells.
Laboratories of Cellular BioTechnologies.

- Institute of Biophysics and Cell Engineering of NAS Belarus (A).
- 9th city clinical hospital, Minsk (A).
- Belarusian Research Center for Pediatric Oncology, Hematology and Immunology (A).
- Republican Scientific and Practical Center of Transfusiology and Medical BioTechnologies (A- in process).
- Republican Research and Practical Center for Epidemiology and Microbiology.
- Belarusian Medical Academy of Post-graduated Education.
Medical organizations, implemented cellular therapy.

- 9th city clinical hospital, Minsk.
- Belarusian Research Center for Pediatric Oncology, Hematology and Immunology.
- Republican Research and Clinical Center of Neurology and Neurosurgery.
- Republican Scientific and Practical Centre for Traumatology and Orthopedics.
- Republican Research and Practice Centre for Mental Health.
- Republican Scientific and Practical Center of Pulmonology and Tuberculosis.
- National Research Center “Mother and Child”.
- N.N. Alexandrov National Cancer Centre of Belarus.
- Minsk 5th city hospital.
- Minsk 4th city hospital.
Current list of diseases and pathologies for cellular therapy in Belarus.

- “Graft versus Host reaction” post bone marrow transplantation.
- Insufficiency of hematopoietic cells for transplantation.
- Transplant rejection post organ transplantation.
- Amyotrophic lateral sclerosis.
- Symptomatic epilepsy.
- Multiple sclerosis.
- Noninfectious lung pathology.
- Noninfectious hepatitis.
- Tuberculosis.
- Osteoarthritis.
- Osteosynthesis.
- Wound healing.
- Stroke.
- Acute leukemia (relapse).
- Cancer (different types).
- Stenosis of trachea.
Comment to first stage of medical implementation of cellular therapy in Belarus (2006 - 2016).

- Mostly autologous cells were used for cellular therapy.
- 24 methods of cellular therapy were approved for clinical use by Ministry of Health the Republic of Belarus.
- Up to 200 patients were treated.
- Cellular therapy was safe in all studies.
- Cellular therapy was effective in drug resistant cases.
- More than 50% of treated patients responded to cellular therapy.
- Price of cellular therapy (approximately 1000 to 5000 belarusian roubles per one cycle of therapy) was covered by Belarusian government.
Nearest perspective list of diseases and conditions for cellular therapy in Belarus.

- Diabetes mellitus.
- Alzheimer’s disease.
- Parkinson’s disease.
- Miscarriage.
- Peripheral arterial disease.
- CMV reactivation post bone marrow transplantation.
- Myeloid leukemia.
- Cancer.
- …..
International cooperation needs in:

- cooperation between specialists groups for research & development of new techniques to prepare biomedical cellular products and their administration;
- cooperation between Centers (Clinics) for multicenter studies of safety and efficiency of new methods of cellular therapy.