CELL TECH PHARMED

Products and Services

HISTORY

Cell tech pharmed, a pioneer company in the field of stem cell and regenerative medicine was established in Feb 2014. The investors of this company, the Pharmaceutical institute and the Verkaan Group have shared their brilliant experience in the field of stem cell and pharmaceutical products.

REGENERATIVE MEDICINE

Regenerative medicine and cell therapy, the most recent and emerging branch of medical science deals with functional restoration of specific tissues and organ of the patients suffering with severe injuries or chronic disease conditions, in the state where bodies own regenerative responses do not suffice.

PIPELINE

According to research was conducted by Pharmaceutical Institute by 2005 and reach to valuable results of clinical trials for the stem cell transplantation in diseases such as arthritis, wrinkles, acne scars, vitiligo and heart failure. Cell Tech Pharmed plant launched to meet the demand of the patients. This plant has created tremendous conditions in the scientific and industrial history of the Iran.

FACILITY

One of the permanent important strategy of this construction is transform cell therapy method from research knowledge to industrial phase. This plant –as the first cell therapy plant in Iran and the Middle East-has capacity to treat of 3000 patients. The design of this production units is intended to be even as a global model.

MISSION AND VISION

Cell Tech Pharmed proudly presents its scientific and medical achievements and contributions to the health and wellbeing of the communities and strives to innovate the cell based medicines that meet the patients changing needs.

NETWORK

Cell Tech Pharmed has a broad network of collaborative relationships with leading research and clinical institutions and is committed to developing a pipeline of novel “best-in-class” medicines. This company had decided to become a global stem cell therapy business that delivering great medicines to patients through innovative science and excellence in development and commercialization.

PRODUCTS AND SERVICES

For patients

For physicians

For investors

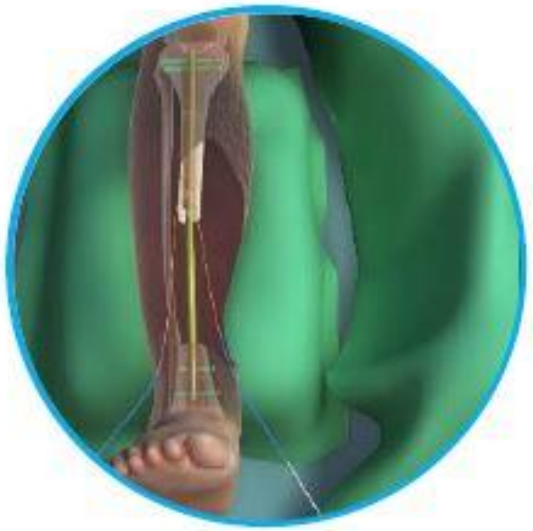
For patients

MESESTROCELL

Autologous cultured bone marrow derived mesenchymal stromal cells

Osteoarthritis

Arthritis rheumatoid



Non union fracture

MESESTROCELL

Autologous cultured bone marrow derived mesenchymal stromal cells

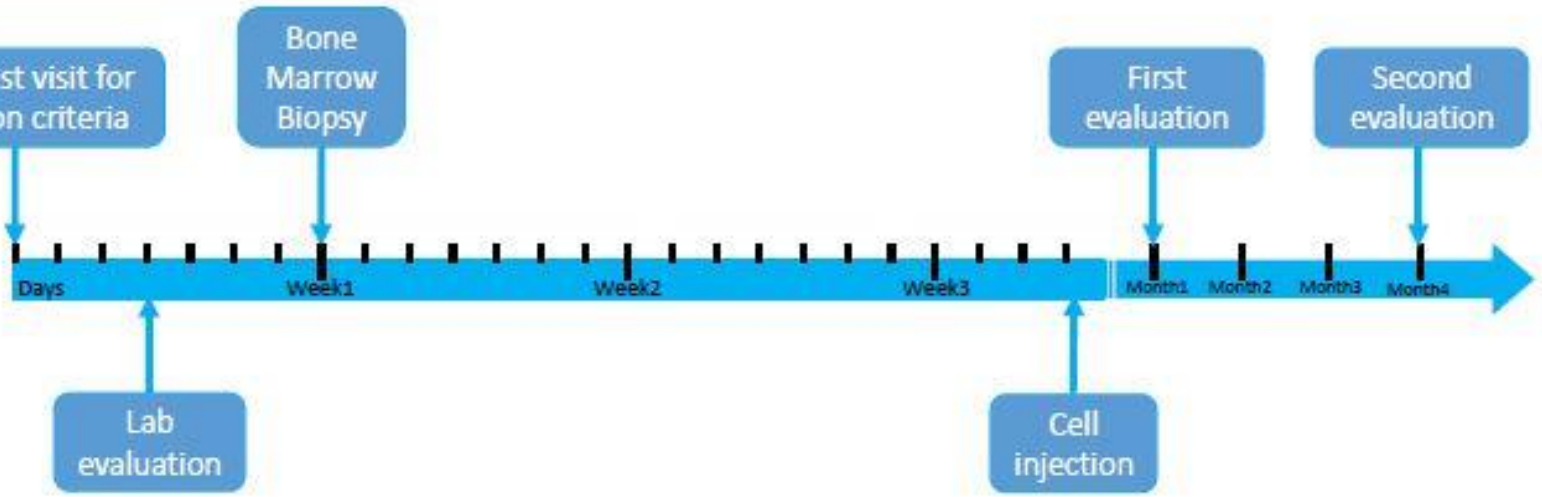
Amyotrophic Lateral Sclerosis

Cerebral palsy

Multiple sclerosis

PROTOCOL

MesestroCell®



Lab list
1- CBC- diff
2- Anti-HBS, Anti-HBC, HBS-Ag, Anti-HCV, Anti-HIV, Anti HTLV-1, Anti-CMV
3-SGPT, SGOT, Bil T&D,
4- Anti-TPO, TSH
5- PT, PTT, INR
6-FBS, HBA1c
7-Chol, TG, HDL
8- BUN, Cr
9-U/A

Biopsy
Position
Iliac Crest
Size
100 -150 ml

Cell injection
Volume
3-5 ml
Cell No.
40-50 10(6)
Position
Intra or IV

Evaluation
1- Depend on diseases

OSTEOARTHRITIS

Osteoarthritis is the most common degenerative disease of joint cartilage and the underlying bone, in middle age onward. It causes pain and stiffness, especially in the hip, knee, and thumb joints.

Criteria

Inclusion

- ❑ Age 18 to 65
- ❑ Established osteoarthritis of knee or hip or ankle joints
- ❑ Kellgren- Lawrence grading of less than 4 severe
- ❑ Knee mal- alignment less than 12 degree toward inside or outside (genu valgum or genu varum)
- ❑ No uncontrolled chronic or acute diseases

Exclusion

- ❑ Knee mal- alignment over than 12 degree toward inside or outside (genu valgum or genu varum)
- ❑ Any uncontrolled chronic or acute diseases

Clinical trials

NCT01207661
NCT01436058
NCT01499056

Published data

1. Mohsen Emadedin, et. al. (2012). Archives of Iranian Medicine
2. Mohsen Emadedin, et. al. (2015). Archives of Iranian Medicine
3. Peng Xia, et. al. (2015). International Orthopaedics (SICOT)

Price	6000 USD	USD

RHEUMATOID ARTHRITIS

Definition

Rheumatoid Arthritis is a chronic progressive disease causing inflammation in the joints and resulting in painful deformity and immobility, especially in the fingers, wrists, feet, and ankles.

Criteria

Inclusion

- ❑ Age 18 to 65
- ❑ Established rheumatoid arthritis according to ACR 2010 criteria.
- ❑ Established osteoarthritis of knee joint
- ❑ Kellgren- Lawrence grading of less than 4 severe
- ❑ Knee mal- alignment less than 12 degree toward inside or outside (genu valgum or genu varum)
- ❑ No uncontrolled chronic or acute diseases rather than RA.

Exclusion

- ❑ Knee mal- alignment over than 12 degree toward inside or outside (genu valgum or genu varum)
- ❑ Any uncontrolled chronic or acute diseases

Clinical trials

NCT01873625

Published data

Soraya Shadmanfar et. al. (2018). Cytotherapy journal, 2018.

Price	7000 USD	USD

NON UNION

Definition

Nonunion is permanent failure of healing following a broken bone unless intervention (such as surgery) is performed. Nonunion is a serious complication of a fracture and may occur when the fracture moves too much, has a poor blood supply or gets infected.

Criteria

Inclusion

- ❑ Age 18 to 65
- ❑ Nonunion of lower limbs
- ❑ No uncontrolled chronic or acute diseases rather than nonunion fracture.

Exclusion

- ❑ Any uncontrolled chronic or acute diseases

Clinical trials

NCT01206179

Published data

1. Narges Labibzadeh, et. al. (2016). CELL JOURNAL(Yakhteh)
2. Mohsen Emadedin, et. al. (2017). CELL JOURNAL(Yakhteh)
3. Gómez-Barrena E. et. al. (2015). Bone

Price	6000 USD	USD

AMYOTROPHIC LATERAL SCLEROSIS

Definition

Amyotrophic lateral sclerosis (ALS) is a rapidly progressive neurodegenerative condition where loss of motor neurons within the brain and spinal cord leads to muscle atrophy, weakness, paralysis and ultimately death within 3–5 years from onset of symptoms. The specific molecular mechanisms underlying the disease pathology are not fully understood and neuroprotective treatment options are minimally effective.

Criteria

Inclusion

- ❑ Age: 18-65 years old
- ❑ Both gender
- ❑ ALSFRS-R≥26
- ❑ FVC≥40%
- ❑ Sporadic ALS

Exclusion

- ❑ Neurological and psychiatric concomitant disease
- ❑ Concomitant systemic disease
- ❑ Treatment with corticosteroids, Ig, and immunosuppressive drugs during 12 months
- ❑ Familial ALS

Clinical trials

NCT02492516
NCT01759797
NCT01759784

Published data

1- Nabavi SM, et al. (2018) . Cell Journal
2- Kuzma-Kozakiewicz M, et al. (2018). Stem Cells Int.

Price	7000 USD	USD

CEREBRAL PALSY

Definition

Cerebral Palsy (CP) is the most common motor disability reason of childhood that occurs secondarily to non-progressive damage in the brain whose development is still ongoing.

Criteria

Inclusion

- ❑ Age 4 to 14 years old
- ❑ Both gender
- ❑ Diagnosis of any kind of cerebral palsy
- ❑ Without or with controlled epilepsy

Exclusion

- ❑ Any neurologic, cardiac/respiratory, infectious or blood disorder
- ❑ Contraindications for MRI
- ❑ Genetic disorders
- ❑ Traumatic brain disorders
- ❑ Severe trauma to brain white tissue

Clinical trials

NCT01404663
NCT01763255

Published data

1- Okur SQ, et al. (2018). Int J Stem Cell.
2- Sun JM, et al. (2017). Stem Cells Transl Med.

Price	7000 USD	USD

MULTIPLE SCLEROSIS

Definition

Multiple sclerosis (MS), is a chronic disease of the central nervous system (CNS) characterized by loss of motor and sensory function, that results from immune-mediated inflammation, demyelination and subsequent axonal damage. MS is one of the most common causes of neurological disability in young adults.

Criteria

Inclusion

- ❑ Relapsing and progressive MS with:
  - Age: 18-55 years old
  - Disease period of 2-10 years
  - EDSS: 3-6.5
  - Not to respond to conventional immunomodulatory or cytotoxic drugs
- ❑ Primary progressive MS with evidence of recurrence or GAD enhancement in MRI
- ❑ Secondary progressive MS with recurrence
- ❑ Secondary progressive MS without recurrence (evidence of disease progression and at least one point increase in EDSS during previous 18 months

Exclusion

- ❑ Pregnancy
- ❑ Receiving cytotoxic or immunomodulatory drugs at the same time or during last 3 months
- ❑ Relapse of the disease less than 30 days before
- ❑ Any severe cognitive disorder
- ❑ Primary progressive MS

Clinical trials

NCT01377870

Published data

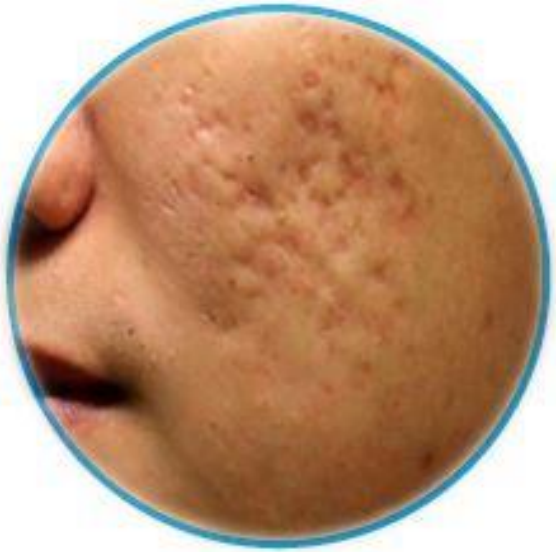
1- Sahraian MA, et al. (2018). Immunol Invest.
2- Harris VK, et al. (2015). Dis Manag.

Price	7000 USD	USD

RenuDermCell®

Autologous cultured dermal fibroblast

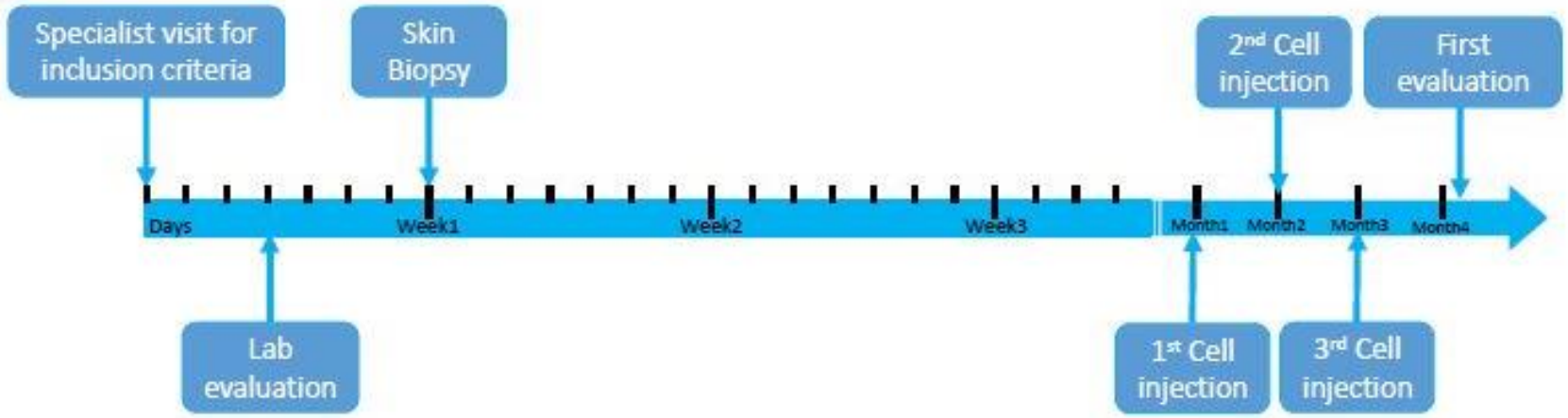
Skin Rejuvenation



Acne Scars

PROTOCOL

RenuDermCell®



Lab list
1- CBC- diff
2- Anti-HBS, Anti-HBC
HBS-Ag, Anti-HCV
Anti-HIV
3- Anti-TPO
4- TSH

Biopsy
Position
Rear Ear
Size
5-6 mm(2)

Cell injection
Volume
1-2 ml
Cell No.
20-30 10(6)
Position
Intradermal

Evaluation
1- Depend on diseases

SKIN REJUVENATION

Definition

Skin aging is a complex, multifactorial process defined by progressive loss in skin integrity and function. Fibroblasts are the main cells of dermis that reduction in the cells' size and amount has known as hallmark of aged skin.

Criteria

Inclusion

- ❑ Mild to severe wrinkles in face, neck, or hands
- ❑ 18 ≤ Age ≤ 65 years old

Exclusion

- ❑ Immune-suppressive drugs, retinoid derivatives, botulinum toxin or temporary fillers during the past 6 months
- ❑ Any known cancer
- ❑ Permanent fillers
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

NCT01115634

Published data

1- Shafieyan S. et al. (2016). J Investig Dermatol
2- Smith SR. et al. (2012). Dermatol Surg

Price	6000 USD	USD

ACNE SCAR

Definition

Acne scars occur in 95% of acne patients even during standard treatments. Local and systemic inflammation following active acne lead to destruction of fibroblasts and consequent collagen loss.

Criteria

Inclusion

- ❑ Mild to severe acne scars
- ❑ 18 ≤ Age ≤ 65 years old

Exclusion

- ❑ Immune-suppressive drugs, retinoid derivatives, botulinum toxin or temporary fillers during the past 6 months
- ❑ Any known cancer
- ❑ Permanent fillers
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

NCT01115634

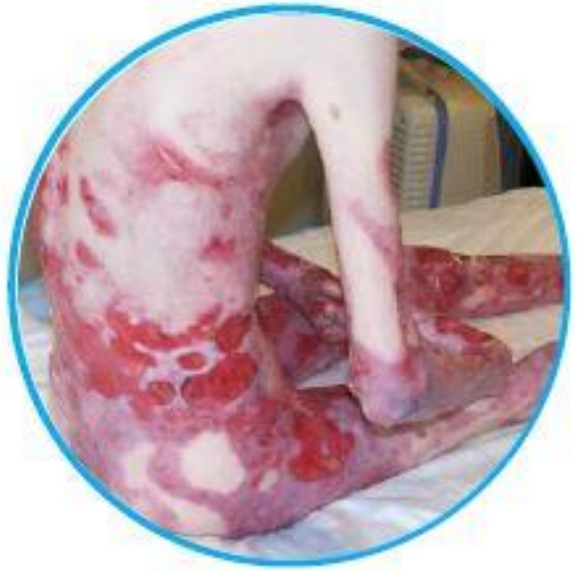
Published data

1- Shafieyan S. et al. (2016). J Investig Dermatol
2- Munavalli GS. Et al. (2013). Dermatol Surg

Price	6000 USD	USD

ReSkinCell®

Cell Based Skin Substitute



Epidermolysis Bullosa

EPIDERMOLYSIS BULLOSA (ALOGENEIC PRODUCT)

Definition

Epidermolysis bullosa (EB) is a genetic disorder that result in easy blistering of the skin and mucous membranes. Blisters occur with minor trauma or friction and are painful. Its severity can range from mild to lethal.

Criteria

Inclusion

- ❑ Chronic, non-healing wounds
- ❑ Mitten hands
- ❑ Age ≥ 2 years old

Exclusion

- ❑ Immune-suppressive drugs during the past 6 months
- ❑ Any known cancer
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

NCT01908088

Published data

1- Petrof G. et al. (2013). Br J Dermatol
2- Wong T. et al. (2008). J Invest Dermatol.

Price	10,000 USD	USD

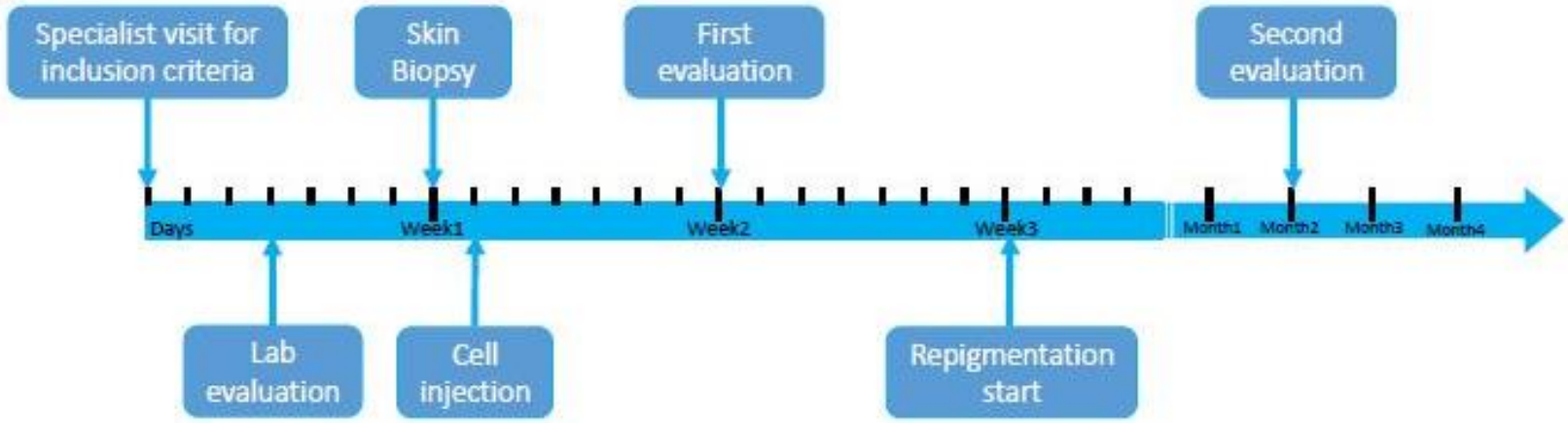
RecolorCell®

Autologous suspended skin cells

Vitiligo

PROTOCOL

RecolorCell®



Lab list
1- CBC- diff
2- Anti-HBS, Anti-HBC
HBS-Ag, Anti-HCV
Anti-HIV
3- Anti-TPO
4- TSH

Biopsy
Position
buttock
Size
5-10 mm(2)

Cell injection
Volume
1-2 ml
Cell No.
10-20 10(6)
Position
Intraepidermal

Evaluation
1- Repigmentation

VITILIGO

Definition

Vitiligo is a common depigmentary disorder characterized by depigmented well-defined multiform patches on skin and sometimes hairs.

Criteria

Inclusion

- ❑ Age> 12 years
- ❑ Disease stability≥ 12 months

Exclusion

- ❑ History of treatment with immunosuppressive or cytotoxic drugs during the last 6 months
- ❑ History of malignancy, chemotherapy, radiotherapy, blood transfusion, and/or organ transplantation
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

NCT00631865

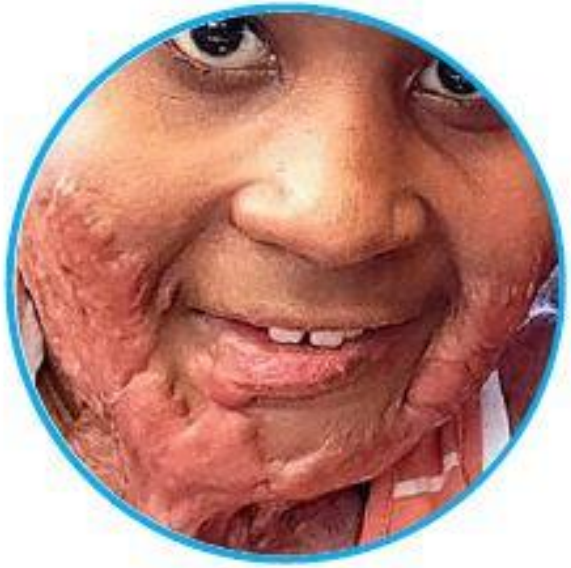
Published data

1. Khodadadi L. et al. (2010). Arch Dermatol Res
2. Orouji Z. et al. (2018). J Dermatol Sci
3. Van Geel N. et al. (2011). J Cutan Aesthet Surg

Price	3500 USD	USD

Lipovascell®

Autologous Stromal Vascular Fraction

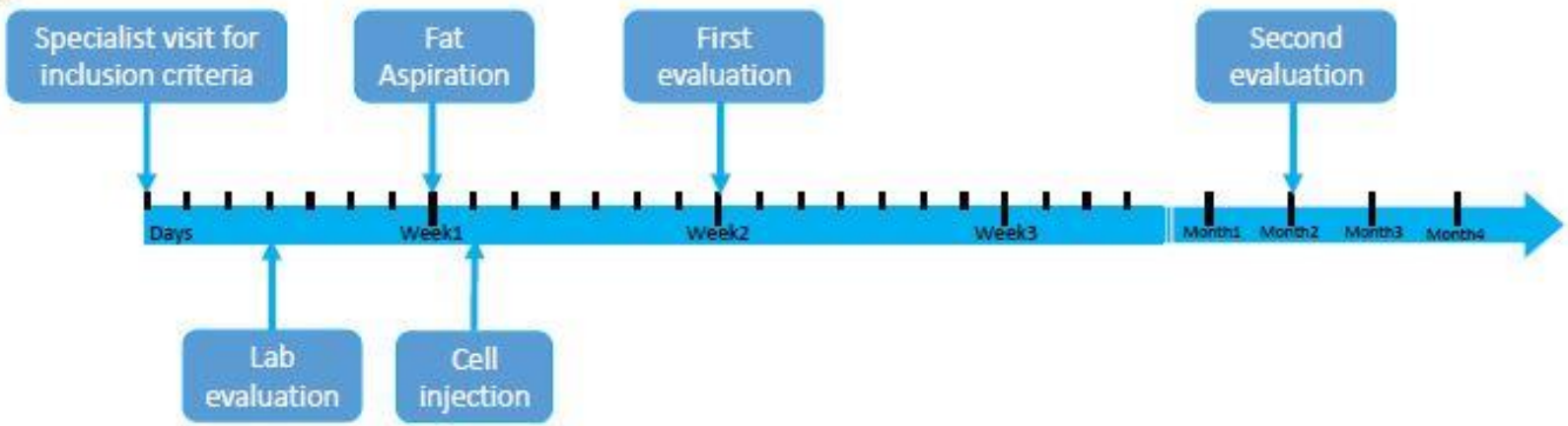


Burn Scars

Cell Assisted Lipotransfer

PROTOCOL

Lipovascell®



Lab list
1- CBC- diff
2- Anti-HBS, Anti-HBC
HBS-Ag, Anti-HCV
Anti-HIV
3- Anti-TPO
4- TSH

Biopsy
Position
Abdomin
Size
40 – 50 ml

Cell injection
Volume
20-25 ml
Cell No.
20-30 10(7)
Position
Intradermal

Evaluation
1- Depend on diseases

BURN SCAR

Definition

Burn scar is a common complication of deep burn injury presenting as a raised inelastic skin tissue, usually associated with pruritus.

Criteria

Inclusion

- ❑ 18 ≤ Age ≤ 65 years old
- ❑ Burn occurrence ≥ 6 months
- ❑ Vancouver Scar Scale ≥4

Exclusion

- ❑ History of immunosuppressive therapy during the 6 months prior to enrolment
- ❑ Any known cancer
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

IRCT2012070710201N1

Published data

1. Bajouri A. et al. (2018). ISSCR poster abstract book [Abstract]
2. Jackson W.M. et al. (2012). Stem Cell Res Ther

Price	5000 USD	USD

CELL ASSISTED LIPOTRANSFER

Definition

Autologous fat grafting is a common procedure for soft-tissue reconstruction but is associated with a graft resorption rate ranging from 40% to 80%. Cell-assisted lipotransfer (CAL) is a new technique in which the aspirated fat is injected along with adipose-derived stromal cells to improve fat survival rate.

Criteria

Inclusion

- ❑ 18 ≤ Age ≤ 65 years old
- ❑ Facial or Breast augmentation

Exclusion

- ❑ Immune-suppressive drugs, retinoid derivatives, botulinum toxin or temporary fillers during the past 6 months
- ❑ Any known cancer
- ❑ Permanent fillers
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

IRCT201612291031N21

Published data

1. Zhou Y. et al. (2016). Plast Reconstr Surg
2. Yoshimura K. et al. (2008). Dermatol Surg

Price	3500 USD	USD

AllaAdCell®

Allogenic Adipose-derived Stromal Cells

Psoriasis

PSORIASIS (ALOGENEIC PRODUCT)

Definition

Psoriasis is an autoimmune skin disease in which life cycle of skin cells is speeded up. It causes cells to build up rapidly on the surface of the skin. The extra skin cells form scales and red patches that are itchy and sometimes painful.

Criteria

Inclusion

- ❑ 18 ≤ Age ≤ 65 years old
- ❑ Chronic plaque psoriasis for at least 6 months
- ❑ No response to standard treatments

Exclusion

- ❑ Immune-suppressive drugs during the past 4 weeks
- ❑ Any known cancer
- ❑ Hepatitis B, hepatitis C or HIV
- ❑ Pregnancy or lactation

Clinical trials

IRCT20080728001031N24

Published data

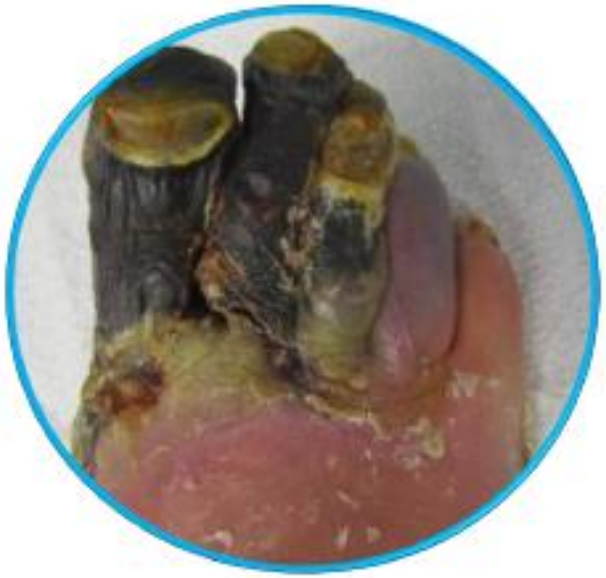
1. Owczarczyk-Saczonek A. et al. (2017). Int J Mol Sci
2. Chen H. et al. (2016). Am J Med

Price	3000 USD	USD

MonuCell®

Autologous Bone marrow derived mononuclear

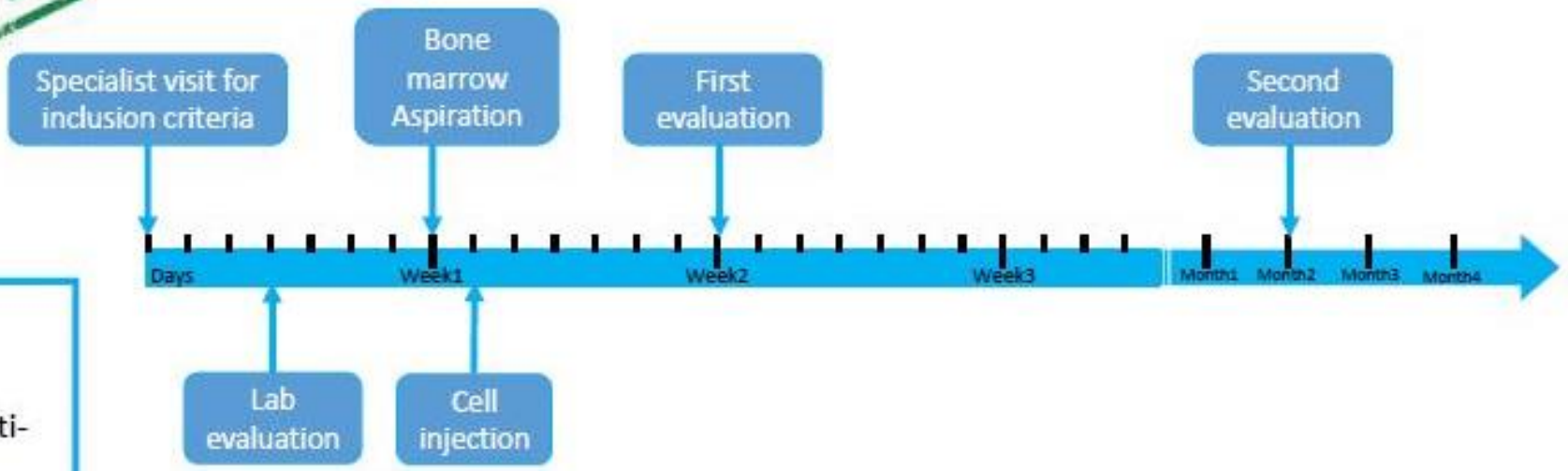
Cardiomyopathy
(Heart Failure)



Chronic Lower Limb
Ischemia

PROTOCOL

MonuCell®



Lab list
1- CBC- diff
2- Anti-HBS, Anti-HBC, HBS-Ag, Anti-HCV, Anti-HIV, Anti HTLV-1, Anti-CMV
3-SGPT, SGOT, Bil T&D,
4- Anti-TPO, TSH
5- PT, PTT, INR
6-FBS, HBA1c
7-Chol, TG, HDL
8- BUN, Cr
9-U/A

Biopsy
Position
Iliac Crest
Size
100 -150 ml

Cell injection
Volume
3-5 ml
Cell No.
40-50 10(8)
Position
intra-lesion

Evaluation
1- Depend on diseases

CARDIOMYOPATHY (HEART FAILURE)

Definition

Heart Failure is when the heart is unable to pump sufficiently to maintain blood flow to meet the body's needs. Signs and symptoms commonly include shortness of breath, excessive tiredness, and leg swelling.

Criteria

Inclusion

- ❑ 18< Age <75
- ❑ LVEF<40% (echocardiography)
- ❑ Ischemic or Dilated Cardiomyopathy (Documented)
- ❑ Resistance to Standard Therapy >1month

Exclusion

- ❑ Congenital Heart Disease
- ❑ Uncontrolled Underlying Disease (Diabetes Mellitus, Autoimmune, Malignancy, Infectious, ...)

Clinical trials

NCT01167751
NCT01187654
NCT02256501

Published data

1- Naseri M.H. et al. (2018). Cell Journal
2- Amin A. et al. (2018). Research in Cardiovascular Medicine
3- Fisher S.A. et al. (2014). Cochrane Database Syst Rev
4- Ahmadi H. et al. (2012). Arch Iran Med
5- Karimabad H.M. et al. (2011). Acta Cardiologica
6- Ahmadi H. et al. (2007). Curr Neurovasc Res

Price	3500 USD	USD

CHRONIC LOWER LIMB ISCHEMIA

Definition

Chronic limb ischemia is peripheral arterial disease that results in a symptomatic reduced blood supply to the limbs. It is typically caused by atherosclerosis (rarely vasculitis) and will commonly affect the lower limbs.

Criteria

Inclusion

- ❑ 18< Age <75
- ❑ Presence of Critical Limb ischemia according to the guidelines of the Transatlantic Consensus Group (TASC) Rutherford grade II or III.
- ❑ Absence of life-threatening complications from the ischemic limb.
- ❑ No sufficient response to best standard care delivered for six weeks.

Exclusion

- ❑ Patients with evidence of infectious disease
- ❑ Uncontrolled Underlying Disease (Diabetes Mellitus, Autoimmune, Malignancy, Infectious, ...)

Clinical trials

NCT00677404
NCT01480414

Published data

Zafarghandi M.R. et al. (2010). Cytotherapy.
Molavi B. et al. (2016). Arch Iran Med.
Abdul Wahid S.F. et al. (2018). Cochrane Database Syst Rev.

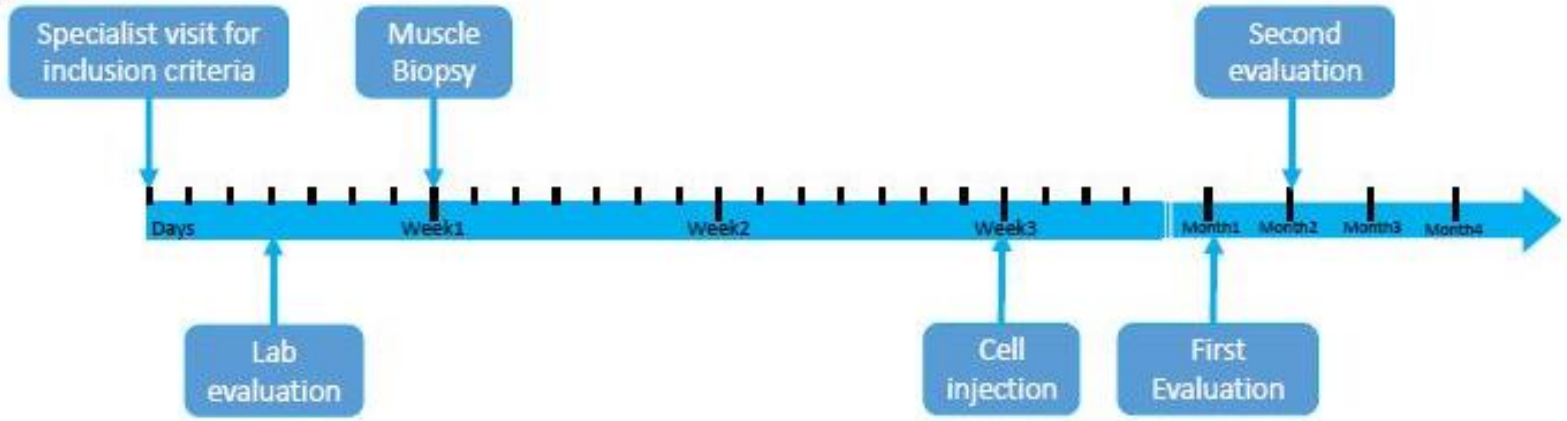
Price	4000 USD	USD

CtrlCell®

Autologous cultured muscle cells

Stress Urinary Incontinence

PROTOCOL



Lab list
1- CBC- diff
2- Anti-HBS, Anti-HBC
HBS-Ag, Anti-HCV
Anti-HIV
3- Anti-TPO
4- TSH

Biopsy
Position
Gastrocnemius muscle
Size
5-6 mm(3)

Cell injection
Volume
1-2 ml
Cell No.
30-40 10(6)
Position
Intra-sphincter

Evaluation
1- Pad Evaluation

STRESS URINARY INCONTINENCE

Definition

(SUI) is a common health problem in women. It has been reported that 25%-35% of women over 18 years of age suffer from urinary incontinence. The International Continence Society defined SUI as the involuntary leakage of urine on exertion, effort, coughing, or sneezing. Few clinical studies have evaluated the safety and efficacy of intraurethral injections of adult stem cells as treatment of SUI.

Criteria

Inclusion

1- Age: 18-65 years old
2- Female
3-SUI accompanied by a hypermobile urethra with a valsalva leak point pressure (LPP) of 60-90 cm H2O

Exclusion

1-having anti-incontinence surgery in the 12 months
2-having evidence of acute vulvovaginitis, cystoceles of equal to or more than grade 3, active urinary tract infection, urogynecologic malignancies, coagulopathies, high grade rectocele, diabetes mellitus (DM), post–void residual volume equal to or more than 100 ml, abnormal cystourethroscopy, and abnormal urodynamic study (low capacity, low compliance, detrusor overactivity).

Clinical trials

NCT02156934
NCT01963455

Published data

Sharifiaghdas F, et al. (2016) International journal of urology.

Price	7000 USD	USD

For physicians

Education Programs

Education programs related to cell therapy and Regenerative Medicine

Workshop

Short term courses

Fellowship

WORKSHOPS AND SHORT TERM COURSES

Topics
➢Regulatory & Ethics Issues ➢Intensive Stem Cell Biology Coursework; ➢Preclinical studies, ➢GMPs, ➢MSC isolation and transplantation and emerging technologies such as IPSc.

Price	500-1500 USD	USD

FELLOWSHIP-CURRICULUM

		Course Unit			Course Hours		
No	Course Name	Theory	Practice	Total	Theory	Practice	Total
1	Principal Of Stem Cell Technology	2	0	2	36	0	36
2	Advanced Cell & Molecular Biology	2	0	2	36	0	36
3	Principal Of Regenerative Medicine	2	0	2	36	0	36
4	Good Manufacturing Practices (GMP)	2	0	2	36	0	36
5	Good Clinical Practice (GCP) –Principles -Essential Documents	1	1	2	18	18	36
6	Good Clinical Practice (GCP) –Advanced -Monitoring Course	1	1	2	18	18	36
7	Regulatory Rules In Cell Therapy And Related Issues	1	0	1	18	0	18
8	Bio Informatics , Research Method , Data Management	1	1	2	18	18	18
9	Tissue Engineering	2	0	2	36	0	36
10	Transplantation Immunology	1	0	1	18	0	18
11	Pathology In Targeted Disease In Cell Therapy	1	0	1	18	18	36
12	Medical Ethics In Human Subject Research	1	0	1	18	0	18
13	Cell Culture And Laboratory Technique	1	1	2	18	18	36
14	Cell Banking For Cell Therapy	1	0	1	18	0	18
15	Experimental Medicine\Work With Small And Large Animal	1	1	2	18	0	18
13	Total	20	5	25	360	90	450

Price	---------- USD	USD

For investors

BUSINESS MODELS OF COOPERATION

- **Strategic Partnership Model:**
  - Official representation in the country of origin
  - Training of medical professionals and professional marketers
  - Dispatched patients to Iran for cell therapy

- **Joint Venture Model:**
  - Establish a stem cell production plant
  - Technology Partner (TP): Know How + Training the specialists+ Managing the Construction
  - Local Partner(LP): Internal Licensing + Land Purchase + Supply of Equipment
- **Technology sales Model:**
  - Sales of technical knowledge
  - Delivery of technical documentation
  - Training for Professionals
  - Construction of the production line

Technology

Clinical grade cell production technology

Technology transfer

Process development

Training

TECHNOLOGY TRANSFER

Cell Tech Pharmed is a cell-based manufacturing company that provides the following services to all worldwide clients as below

Services

- Development and Manufacturing Step: Manufacturing Processes, packaging and cleaning methods.
- Analytical Methods such as QC, QA and IPQC
- In-site and on-site trainings
- Technology transfer procedure management
- Facility design
- Documentation
- Qualification and Validation

PROCESS DEVELOPMENT/SCALE UP

Cell Tech Pharmed can develop customized processes together with its needs for tailor-made products. Cell Tech can adapt the manufacturing process precisely to the client's needs. The main area of interest in process developments are as follows

Services

- Cell line, Autologous and Allogenic cell-based products Development and Manufacture.
- Analytical Method Development
- Clinical Trial Material Manufacturing, Packaging & Labeling
- Process Qualification/Continued Process Verification

PROCESS DEVELOPMENT/OPTIMIZATION

Services

Optimization of Process for the purpose of maximizing quality, scalability, and reproducibility including:

- Cell culture configuration
- Culture Media design and optimization
- Passage and Cell Expansion
- Cryopreservation methods

Process Development can be tailored to client needs, including:

- Develop open and closed culture systems.
- Scale out or scale up cell culture methods.
- Capacity evaluation in order to determine an appropriate processe
- Stability studies
- Transition to a Phase I/II compliant manufacturing process
- Develop Analytical method to evaluate safety, identity and purity
- Scale up the process to manufacture according to GMP conditions

TRAINING

We train on the fundamentals of the technology processes and on application-specific processes. On request, we also organize special training courses. Cell Tech can provide the following trainings per clients requests

Services

- Overview of cell therapy Concepts and methods.
- Aseptic manufacturing processes
- Cell counting and viability
- Cell Isolation technologies
- Transduction and vectors
- Cell culture media development and design
- Cell expansion and Passage
- Harvesting Methods
- Cryopreservation Methods
- Development of standard operating procedures
- Process optimization, Validation and continues verifications

Engineering services

Cell production facility

Engineering, procurement, and construction

Consultation

ENGINEERING, PROCUREMENT, AND CONSTRUCTION

Cell Tech offers the following services within an EPC/Turnkey contract

Services

- Selection of suitable technology
- General concept studies and design
- Basic Engineering design
- Detail Engineering in all design disciplines
- Construction (Construction subcontractor)
- Supervision
- Procurement of all necessary equipment
- Commissioning
- personnel training
- As Built Documentation
- Qualification and Validation

CONSULTATION

Cell Tech Pharmed provides assistance and Consultant at all stages of cell-based Products development to clients. With its deep experience, Cell Tech team of expertise provide professional advice and services related to Clinical and nonclinical safety and efficacy testing, manufacturing, clinical trial design, and more

Services

Cell-based Products Consulting Services are as below:

- New Product Development
- Analytical and QA
- Product portfolio and business model and marketing
- Cell-based manufacturing facility design and construction
- Process design, optimization and validation

Marketing

Cell product business

Feasibility studies

Marketing strategies

FEASIBILITY STUDIES

Cell Tech has a deep experience in feasibility studies as below

Services

- **Initial analysis of projects**
  - Information assessment and collection
  - Initial analysis of the proposed development area
  - Conduct land or site review
  - Proposed construction and development costs
- **Market analysis**
  - Demographic analysis of the proposed area
  - National and international market overview
  - Analysis of similar project and developments
  - Competitive market analysis
  - Competitive advantages and disadvantages of the projects or locations
  - Market insight
  - Pricing analysis & Purchase behavior
- **Financial analysis**

MARKET RESEARCH

Cell Tech expertise undertake a variety of market research projects within the medical and pharmaceutical market. Cell Tech conducts researches among doctors and other medical staffs, pharmacists, patients, hospital managers and opinion leaders

Services

- **The most common types of Cell therapy market researches:**
  - patients' opinions and behavior,
  - physicians' therapy and prescription habits,
  - pharmacists' recommendations,
  - satisfaction studies (e.g. cooperation with medical representatives),
  - name, packaging and advertising concept testing,
  - pricing and reimbursement schemes,
  - pre-market launch studies.

MARKET RESEARCH

Cell Tech conducts several annual primary healthcare research reports which focuses on the pricing and reimbursement issues. Using a unique multi-client study methodology, Cell Tech's expertise conduct more than 200 interviews and supplement this with the best secondary sources for each study. In these cases, clients eagerly work with Cell Tech to

Services

- Understand the business impact and the key issues of the industry
- pricing and life cycle strategies Development
- Monitoring and controlling competitors and customers
- Assess business impact based on new regulations
- budgets Planning and forecasts
- Keep pace with market, technology and regulatory trends

MARKET RESEARCH

Services

- **The market-research project can be generally be broken into the following steps:**
  - Analysis the research objectives
  - Selection an appropriate research design
  - Derivation and formulation of research questions
  - Selection the study method/recruitment
  - Data collection
  - Statistical analysis data's
  - Interpretation of statistical analysis

Contract Manufacture

Your Concept. Our Expertise

GMP Processing Rooms

Quality Control Laboratory

CONTRACT MANUFACTURE

Cell Tech is has a high experience in regenerative medicines which guarantees the highest quality for the most demanding requirements. Cell Tech manufacturing site is a cGMP compliant clinical cell-based manufacturing facility, designed specifically to meet the needs of cell-based therapy clients. state-of-the-art manufacturing Cleanrooms of Cell Tech includes ISO Class 5 (Class B) which suites the designed for European regulatory needs.

Services

- Unidirectional flow design for materials and personnel.
- Full equipped QC lab.
- Emergency power systems.
- Independent HVAC systems for all clean area.
- Validated manufacturing equipment.
- Excellent technical and support staffs.
- Adequate space for expansion into commercial production scale.

JOINT VENTURE

Cell Tech Pharmed eagerly looking forward to working with their competitors, new Companies and Investors to gain a positive synergy from its Corporations. We believe that Joint Venture agreement will help both the companies to scale up their limited capacity and The strength of this agreement will give them more competitive advantages to generate economies of scalability and reduce the risk of entering the new markets.

In our Joint venture agreement, we will provide the recipes and expertise of its various autologous stem cell technologies and our partner will provide its infra-structure i.e. its lab facilities, Scientists and other ancillary services and will be responsible for the production and to sell the finished products to the JVC with cost to be determined on a case to case basis.

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Assumption of Joint venture's Feasibility Study

Joint Venture Project	
Construction Phase	3
Production Phase	10
Max Discounting Rate	10%
Min Discounting Rate	8%
Long term Loan Rate	5%
of Loan %	%0
Number of Products	5
Tax Rate	10%
Currency	$
Cost contingency rate	3%
Marketing Cost per Revenue	15%

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Summery of Investment

Items	Joint Venture Project		Total
Investment Cost	Fix Investment Cost	14,702,600	19,948,129
	Pre-production cost	4,200,000	
	Working Capital	1,045,529	
Source of Finance	Equidity	19,948,129	19,948,129
	Loan	0	
	IRR	***11.11%***	
	IRRE	***11.11%***	
	NPV	***1,262,963***	
	NPVE	***1,262,963***	

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Land Purchase and Civil Work

Land purchase				
No	Item	Quantity	Price	Total
1	*Land*	*2,000*	*250*	*500,000*

Site Preparation and Civil work				
No	Item	Quantity	Price	Total
1	Pre-construction	2,000	100	200,000
2	Clean room B	1,000	2,500	2,500,000
3	Clean Room C	500	1,200	600,000
4	Clean Room D	500	500	250,000
5	CNC	200	300	60,000
6	Office	500	200	100,000
7	Warehouse	300	300	90,000
	Total	*5,000*		*3,800,000*

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Know-How and Technology Cost

Know-How		
No	Item	Price
1	*Cell production Know-how*	*5,000,000*

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Total Fix Cost of Investment

No	Items	Cost
1	Land	500,000
2	Civil Work	3,800,000
3	Know-How	5,000,000
4	Production Equipment	5,000,000
5	Others	120,000
6	Contingencies Cost	282,600
Total Fix Investment Cost		***14,702,600***

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Total Pre-Production Cost

No	Items	Cost
1	Labor	1,200,000
2	Clinical Trials	2,500,000
3	Others	500,000
Total Cost		***4,200,000***

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Total Investment Cost

No	Items	Cost
1	Total Fixed Investment cost	14,702,600
2	Pre-production Cost	4,200,000
3	Working Capital	1,045,529
Total Investment Cost		***19,948,129***

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Products

No	Product	Treatment	Unit	Nominal Capacity
1	Renudermcell (Autologous Fibroblast cell derived from skin)	Wrinkle and Acne scare	Patients	150
2	Recolorcell (Autologous Melanocyte Keratinocyte Derived from Skin)	Vitiligo	Patients	800
3	Lipovascel (Autologous Stromal Vascular Fractional cell derived from Adipose Tissue)	Cell Assisted Lipotransfer	Patients	750
4	Mesestrocell (Mesenchymal Stromal cell derived from Bone Marrow)	Knee & Hip Osteoarthritis	Patients	800
5	Monucell (Mono nuclear cells Derived from Bone Marrow)	Acute Myocardial Infraction	Patients	500
Total				3,000

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Price of Products and Total Revenue

No	Items	quantity	Sales Price	Total Revenue
1	Wrinkle and Acne scare	150	3,000.0	450,000
2	Vitilago	800	2,500.0	2,000,000
3	Cell Assisted Lipotransfer	750	1,500.0	1,125,000
4	Knee & Hip Osteoarthritis	800	4,500.0	3,600,000
5	Acute Myocardial Infraction	500	8,000.0	4,000,000
Total Revenue				11,175,000

PRE-FEASIBILITY STUDY OF JOINT VENTURE

IRR Calculation

Items	*Years*												
	1	2	3	4	5	6	7	8	9	10	11	12	13
Total Fix investment Cost	4,240,520	6,541,040	3,921,040										
Pre-Production Cost	1,680,000	1,680,000	840,000										
Working Capital			1,045,529	0	128,233	170,978	42,744	0	0	0	0	0	0
Tax				7,958	114,769	257,185	292,789	292,789	384,949	384,949	384,949	384,949	384,949
Production cost				6,625,425	7,233,556	8,044,399	8,247,109	8,247,109	7,325,509	7,325,509	7,325,509	7,325,509	7,325,509
Out flow	5,920,520	8,221,040	5,806,569	6,633,382	7,476,559	8,472,561	8,582,643	8,539,898	7,710,458	7,710,458	7,710,458	7,710,458	7,710,458
Operational Revenue				6,705,000	8,381,250	10,616,250	11,175,000	11,175,000	11,175,000	11,175,000	11,175,000	11,175,000	11,175,000
Non-Operational Revenue													4,333,744
Depression				1,636,434	1,636,434	1,636,434	1,636,434	1,636,434	714,834	714,834	714,834	714,834	714,834
In-flow	0	0	0	8,341,434	10,017,684	12,252,684	12,811,434	12,811,434	11,889,834	11,889,834	11,889,834	11,889,834	16,223,578
Net Flow	-5,920,520	-8,221,040	-5,806,569	1,708,052	2,541,125	3,780,123	4,228,791	4,271,536	4,179,376	4,179,376	4,179,376	4,179,376	8,513,120
IRR	***11.11%***												
NPV	***1,262,963***												

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Assumption of Joint venture's Feasibility Study – First Scenario

1. 50% of Finance source is Loan

Joint Venture Project	
Construction Phase	3
Production Phase	10
Max Discounting Rate	10%
Min Discounting Rate	8%
Long term Loan Rate	5%
% of Loan	%50
Number of Products	5
Tax Rate	10%
Currency	$
Cost contingency rate	3%
Marketing Cost per Revenue	15%

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Summery of Investment first Scenario

Items	Joint Venture Project		Total
Investment Cost	Fix Investment Cost	14,702,600	20,353,452
	Pre-production cost	4,605,322	
	Working Capital	1,045,529	
Source of Finance	Equidity	9,974,065	20,353,452
	Loan	10,379,387	
	IRR	***11.20%***	
	IRRE	***15.37%***	
	NPV	***1,362,770***	
	NPVE	***3,644,279***	

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Assumption of Joint venture's Feasibility Study – Second Scenario

1. 2 Allogenic Product are added.
2. 4,000,000 extra cost will be added to the plan for conducting Clinical Trial for them.
3. Allogenic Product will be on market in 3 year of production phase.
4. 1,000,000 will be added to Know-How Cost.

Joint Venture Project	
Construction Phase	3
Production Phase	10
Max Discounting Rate	10%
Min Discounting Rate	8%
Long term Loan Rate	5%
% of Loan	%0
Number of Products	7
Tax Rate	10%
Currency	$
Cost contingency rate	3%
Marketing Cost per Revenue	15%

PRE-FEASIBILITY STUDY OF JOINT VENTURE

Summery of Investment– Second Scenario

Items	Joint Venture Project		Total
Investment Cost	Fix Investment Cost	16,732,600	21,597,877
	Pre-production cost	8,400,000	
	Working Capital	805,490	
Source of Finance	Equidity	22,578,090	21,597,877
	Loan	0	
	IRR	16.91%	
	IRRE	16.91%	
	NPV	14,150,070	
	NPVE	14,150,070	

THANK YOU

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