



Power to Transform Lives

Bioeconomy to Bioeconomy-USD 100 Bn By 2025
Led by Department of Biotechnology, Govt. of India

21-23 NOVEMBER 2019 • AEROCITY, NEW DELHI

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Biotechnology Industry Research Assistance Council (BIRAC)

(A Govt. of India Enterprise)

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**LAB
TO
MARKET**
Biotech Products/
Technologies of Startups
Supported by BIRAC
2019

Regrow Cell Therapy Platform for Human Cell and Tissue-based Products



Unique Selling Point

- Regrow Biosciences is a biotechnology organization focused on the research, development and commercialization of regenerative medicine-based cellular therapies. This technology aims to provide biological and curative clinical benefits to patients with disability and life-threatening medical conditions.
- **Lead Products include:**
 - **OSSGROW[®]** - Autologous Cell Therapy for Bone Regeneration, indicated for the treatment of avascular necrosis of hip joint. It can also be applied for non union fractures, bone dysplasia, and spine & maxillofacial applications.
 - **CARTIGROW[®]** - Autologous Cell Therapy for cartilage repair, indicated for treatment of Cartilage Defects of Knee.
- **Innovativeness:** Regrow products are curative not just managing disease. Autologous Cell therapy for bone and cartilage regeneration uses the patient's own cells thus rendering complete safety.

CELL THERAPY PROCESS



Geographical Region Targeted

Pan India & International markets like US, Europe, Japan & China



Cost

OSSGROW : INR 1.4 Lakhs (Approx 2000 USD)
CARTIGROW : INR 1.4 Lakhs (Approx 2000 USD)



Sold

Products are made accessible at various government & private hospitals.



Product Positioning

- **B2B** :Orthopedic surgeons specializing in Trauma, sports medicine and joint replacement specialists. Widely used in both private Government hospitals.



National/Societal Relevance

- Regrow Cell Therapy products and procedures are biological, minimally invasive and curative .
 - The disease progression is ceased, the patient is free of pain and hence, no further revision surgery required.
 - Patient activity levels are restored, including getting back to professional level sports.
- National Impact:** Dependence on foreign metal implants will be reduced & replaced by Indigenous biological cell-based products.



IP Status

- 32 patent applications have been filed globally in India & in major international markets like US, Europe, China, Japan, Singapore & Africa



Import Substitution

- Potential to save import costs worth \$ 400-500 Mn.



Export Potential

- The product can be exported to various international markets & can generate revenue of over more than \$1 Billion in next 5 years.
- Seamless Cold Chain logistics technology for Scale-UP.



Major Achievements (include awards)

- Conducted successful Multicentric Phase 3 clinical trials in India for the first two Cell-based products for orthopedic conditions.
- India's first two Cells based Drugs received approval from Drug Controller General of India, Ministry of Health & Family Welfare, GoI 2017.
- OSSGROW[®] (Bone Cell therapy) has been granted Orphan Drug Designation from USFDA in 2018 and from EMA (Europe) in 2019.



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INNOVATION PROFILES 2019

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REGROW BIOSCIENCES PVT. LTD.

Title of the Proposal

A Prospective, Open-label, Multicentric Study to Assess the Safety and Efficacy of Autologous Adult Live Cultured Buccal Epithelial Cells Uregrow™ in Subjects with Urethral Stricture

Brief description

To overcome the problem of Urethral Stricture, a cell based product, Uregrow Autologous Adult Live Cultured Buccal Epithelial Cells with advantages like minimally invasive, less post-surgical complications, allows reconstruction of larger urethral strictures up to 04 cm, less post-surgery erectile dysfunction and surgery procedure with 30 minutes as compared to other available treatment procedures.

Current stage of development

Validation

Innovative Element(s)

Recurrence of urethral stricture after urethroplasty is very high. New Innovative developed product Uregrow™ for treating urethral stricture benefits less painful, local implantation with minimum invasion and faster recovery

Market Potential

In 2019, urethral stricture market in India was expected to be 73.9 USD which can be expected to 109.3 USD by the year 2024 at a CAGR rate of 8.16% as per global market report.

National/Societal Relevance

No similar product or technology in the world till date. To offer this treatment to patients with unmet medical need and improve the standard of care for this disease.

Project achievements:

- Progress vis-a vis objectives-** Successfully completed the clinical trial as per objectives
- Technology/Product (to be) developed** – Permanent curative, easy method, minimally invasive procedure and, implantation can be done easily via cystoscopy.
- IP generated/ Potential for IP generation** - Completed national phase filing of the proposed product with patent Application number 201621038900
- Resources Generated** - More than 20 people trained in cell culture and analysis of cells and conducted Phase IIb clinical trial

Plans to take innovation further

In India, take to market and commercialize, for China- working on technology transfer, USA & EU- Registration of the biological product by early next year in 2020.

Risks envisaged

Regulatory issues.



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