BioGenCell
Unique Therapy for Unique People

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Expanded Access Policy for Clinical Investigational Cell Therapy Product (BGC101)

1. **Introduction:**
   - BioGenCell Ltd., ("**BioGenCell**"), Is a biotechnology company specializing in personalized cell therapy for degenerative microvascular diseases.
   - BGC101, is an investigational cell therapy product currently under clinical development for the treatment of Critical Limb Threatening Ischemia (CTLI) and not yet approved by Regulatory Authorities ("BGC101").

   BGC101 is produced from the patient's own blood donation and is composed of Enriched Endothelial Progenitor Cells, Hematopoietic Stem/Progenitor Cells, Activated Dendritic Cells, and T Helper Cells (EnEPC).

2. **Purpose:** This document outlines BioGenCell's policy for considering expanded access requests and providing BGC101 for compassionate use/expanded access to individual patients or groups of patients, who have no other treatment options and who are not eligible or cannot be enrolled in BioGenCell's clinical studies.

3. **Scope:** This policy applies to expanded access requests from healthcare providers for the use of BGC101 for individual patient or groups of patients.

4. **Key Terms Definition:**
   - **Expanded Access / compassionate use**: The access to investigational cell therapy products of individual patients who have no other treatment options and who are not eligible or cannot participate in BioGenCell's clinical studies.
   - **Healthcare Provider**: Any person or organization who is licensed to supply health care.
   - **Treatment Protocol**: A document detailing the plan for using BGC101, investigational cell therapy product in patients with CTLI.

5. **Informed Consent Form**: A document with adequate information about the potential risks, benefits, and alternatives of the investigational cell therapy product, enabling patients to make an informed, voluntary decision about whether to participate in the expanded access program.

6. **General Principles:** BioGenCell's goal is to develop safe and effective therapies. Clinical trials are the main pathway to access investigational drugs, but if patients are ineligible for BioGenCell clinical trial, BioGenCell will consider expanded access for these patients.

7. **Eligibility Criteria:**
   - The patient cannot be participating in any clinical study.
   - The patient has a serious or life-threatening condition such as CTLI with no comparable or satisfactory alternative therapies.
   - The patient is ineligible for, or otherwise cannot enrolled in BioGenCell's clinical trials.

- There is sufficient evidence of a projected benefit from the use of the investigational cell therapy product BGC101, and the benefit outweighs the known or anticipated risks for patients with CTLI.
- Providing the investigational cell therapy product BGC101 for the requested use will not interfere with the initiation, conduct, or completion of active clinical trials or the development of the product

8. Process

- The healthcare provider will submit a request, including patient history and justification for eligibility.
- BioGenCell will evaluate the patient eligibility and will notify the healthcare provider of the decision.
- BioGenCell and Healthcare Provider will draft the treatment protocol and informed consent form (ICF). The healthcare provider will obtain patient signature on the ICF and ensure patient's awareness that BGC101 has not been shown effective in the treatment of CTLI.
- BioGenCell will submit the treatment protocol to Regulatory Authorities for approval and the healthcare provider will submit the treatment protocol for IRB/EC approval.
- Only after signing an agreement regarding the treatment protocol by BioGenCell and the Healthcare Provider, BioGenCell will be committed to the treatment.

9. Roles and Responsibilities

Healthcare Provider: Submits the expanded access request to BioGenCell, provides patient-specific information, obtains ethics committee approval (i.e. IRB/EC), ensures patient monitoring and reporting in compliance with the Treatment Protocol, and reports any side effects to BioGenCell.

The Healthcare Provider is responsible for submitting safety reports to BioGenCell. The healthcare provider is responsible for covering the cost of protocol activities.

BioGenCell: Reviews expanded access requests from Healthcare Provider, submits treatment protocol for approval by Regulatory Authorities and provides BGC101 (the investigational cell therapy product). BioGenCell is responsible for submitting safety reports provided by the Healthcare Provider to Regulatory Authorities.

BioGenCell shall not cover any Expanded Access related costs.

10. **Confidentiality:** The Healthcare Provider and BioGenCell will save the confidentiality of the personal data received from the patient.
11. **Policy Review and Updates:** This policy will be reviewed and updated regularly to align with new regulations and standards.
12. **Contact Information:** For more information or to submit a request, healthcare providers can contact BioGenCell at info@BioGenCell.Net or +972-9-8609248.