

## SPECIFICATIONS

Cell line characterization service, according to standard protocols and standard reports in accordance with GMP regulations, aimed at the release of a 3t3 mouse embryonic fibroblast cell bank to be used as a feeder layer in the production of a gene therapy product indicated for the treatment of patients affected by recessive dystrophic epidermolysis bullosa caused by loss-of-function mutations in the col7a1 gene, which encodes type VII collagen, i.e. the constituent of the anchoring fibrils that ensure dermo-epidermal adhesion, provided by BioReliance Ltd.

**CUP Code E83C22006230001**

### ART. 1 - NATURE OF THE SUPPLY

Direct award procedure pursuant to art. 50, paragraph 1, letter b), of Legislative Decree 36/2023 for the provision of the cell line characterization service, according to standard protocols and standard reports in accordance with GMP regulations and aimed at the release of a 3t3 mouse embryonic fibroblast cell bank to be used as a feeder layer in the production of a gene therapy product indicated for the treatment of patients affected by recessive dystrophic epidermolysis bullosa caused by loss-of-function mutations in the col7a1 gene, which encodes type VII collagen, i.e. the constituent of the anchoring fibrils that ensure dermo-epidermal adhesion for research activities at the Tumor Gene Therapy Research Unit, belonging to the Oncohematology Research Area of the Bambino Gesù Pediatric Hospital, within the Project - Hub Life Science – Advanced Therapy (LSH-TA) PNC-E3-2022-23683269 - Funded by the Ministry of Health as part of the National Complementary Plan for the Innovative Health Ecosystem.

For anything not expressly provided for in the cited sources, reference is made to the provisions of the Civil Code and all applicable laws.

### ART. 2 - DOCUMENTS RELATING TO THE CONTRACTUAL RELATIONSHIP

The contractual relationship, relating to the procurement procedure in question, will be governed by the clauses of these Specifications as well as by the following documentation, which constitutes the integral manifestation of all agreements between the "Bambino Gesù" Children's Hospital ("OPBG") and BioReliance Ltd. (hereinafter the Company or Supplier):

- Invitation Letter;
- Technical Specifications;
- Acknowledgement of Invitation Letter with Financial Offer;
- DGUE;
- Contract

The Hospital reserves the right to verify compliance with the general requirements set forth in the declarations made by the Supplier.

### **ART. 3 - SCOPE OF THE SUPPLY**

These Specifications concern the provision of cell line characterization services, according to standard protocols and standard reports in accordance with GMP regulations, for the release of a 3t3 mouse embryonic fibroblast cell bank to be used as a feeder layer in the production of a gene therapy product indicated for the treatment of patients with recessive dystrophic epidermolysis bullosa caused by loss-of-function mutations in the col7a1 gene, which encodes type VII collagen, the constituent of the anchoring fibrils that ensure dermal-epidermal adhesion. The product is provided by BioReliance Ltd. for research activities at the Tumor Gene Therapy Research Unit, part of the Oncohematology Research Area of the Bambino Gesù Children's Hospital, as detailed in the Technical Specifications.

### **ART. 4 - SUPPLY AMOUNT**

The total amount of this supply will be that offered by the Company, for an estimated amount, for the entire duration of the project, equal to Euro 60,882.65 (sixty thousand eight hundred and eighty-two/65) plus VAT, where applicable.

### **ART. 5 – LOCATION OF SUPPLY**

Delivery of the supply includes all costs related to packaging, transportation, portorage, and delivery and must take place at the locations, times, and quantities indicated from time to time in the Purchase Order (PO), with written notification to the Hospital's Cancer Gene Therapy Research Unit of the actual delivery date. Deliveries must be made to the Pharmaceutical Workshop Warehouse floor, Viale F. Baldelli 38, 00146 Rome.

The Company undertakes to deliver all the above supplies without any additional charges, safeguarding the needs of the OPBG, without hindering, disrupting, or interrupting any ongoing work activities.

The Company further waives any claim or request for compensation in the event that delivery is hindered or made more costly by the activities performed by the OPBG and/or third parties.

The resources responsible for delivering supplies to OPBG will be able to access the site in compliance with all relevant safety and access regulations.

The Company, therefore, must ensure that the technical personnel performing the aforementioned services have been trained to ensure their safety.

OPBG is exempt from any liability in relation to the above.

### **ART. 6 - SUPPLY EXECUTION TERMS**

The supply in question must be completed according to the timeframes and deadlines indicated from time to time in the Purchase Orders (POs) issued by the Hospital, with written notification of the actual delivery date to the Hospital's Cancer Gene Therapy Research Unit.

### **ART. 7 - DELAY PENALTY**

For each day of delay beyond the scheduled delivery date, a penalty equal to 1% of the value of the supply will be applied. The penalty may in no case exceed 1/10 of the total amount. In the event of repeated delays (over twenty days) in delivery, the OPBG may declare the contractual provision

terminated and take all necessary steps to compensate for any damages resulting from the total or partial performance of the supply.

For details on the penalty application procedure, please refer to the Contract.

#### **ART. 8 - PAYMENT**

The Company will issue invoices for the consideration following OPBG's acceptance of the supply. If acceptance is unsuccessful, the invoice cannot be issued unless the failure is attributable to OPBG itself.

Invoices must:

- (i) include references to the Contract and related Purchase Orders;
- (ii) contain, at the bottom, the wording "Invoice bearing a non-transferable credit";
- (iii) indicate the Supplier's bank details for payment by OPBG;
- (iv) indicate the reference CUP code E83C22006230001

Invoices must be sent electronically via the Revenue Agency's System Data Interchange (SDI) with the following information:

- Company name: Bambino Gesù Children's Hospital
- Headquarters address: Piazza Sant'Onofrio 4, 00165 Rome
- Tax code: 80403930581
- Recipient code: SDI QRL4YE1

Electronic invoices must be submitted with a PDF copy of the invoices themselves and the necessary technical explanatory documents, free of sensitive or special data in accordance with applicable data protection legislation.

OPBG will pay invoices within 30 (thirty) days of the invoice date.

The invoice will be paid after verifying compliance with social security contributions through the acquisition of the DURC (Duration of Retirement and Retirement Benefits) declaration.

Any errors, incompleteness, or omissions in the data reported in the invoices pursuant to the above, or inconsistencies in the technical explanatory documents, as well as non-compliance with current legislation, will result in OPBG rejecting the invoices. Therefore, OPBG will not be able to proceed with payment and will consequently not be required to pay any late payment interest requested by the Company.

#### **ART. 9 – GUARANTEE**

Pursuant to Article 117 of Legislative Decree No. 36/2023 and subsequent amendments, the Supplier Company, upon signing the contract, must provide a guarantee, called a "final guarantee," at its discretion, in the form of a surety bond or surety bond, as per the terms set forth in Article 106, paragraphs 2 and 3, equal to 10 percent of the contract amount. This guarantee must be in the form of government-guaranteed public debt securities, a bank guarantee, an insurance policy, or cash at the bank chosen by the Company.

Pursuant to Article 117, paragraph 8, 106 *"The amount of the guarantee and its possible renewal is reduced by 30 percent for economic operators to whom the quality system certification compliant with the European standards of the UNI CEI EN 45000 series and the UNI CEI EN ISO/IEC 17000 series is issued by accredited bodies, pursuant to the European standards of the UNI CEI EN 45000 series and the UNI CEI EN ISO/IEC 17000 series. The 50 percent reduction, which cannot be cumulated with*

*that referred to in the first period, applies to of micro, small, and medium-sized enterprises and groups of economic operators or ordinary consortia consisting exclusively of micro, small, and medium-sized enterprises. The amount of the guarantee and its possible renewal is reduced by 10 percent, cumulative with the reduction referred to in the first and second sentences, when the economic operator presents a surety, issued and digitally signed, which is managed through the use of platforms operating with technologies based on distributed ledgers pursuant to paragraph 3. The amount of the guarantee and its possible renewal is reduced by up to a maximum of 20 percent, cumulative with the reductions referred to in the first and second sentences, when the economic operator possesses one or more of the certifications or marks identified, among those provided for in Annex II.13, in the initial tender documents which also establish the amount of the reduction, within the aforementioned maximum limit. In the event of cumulation of reductions, the subsequent reduction is calculated on the amount resulting from the previous reduction.*

*To benefit from the reductions referred to in this paragraph, the economic operator must indicate, in the offer, that it meets the relevant requirements and document this in the manner prescribed by the applicable regulations.*

*Upon initial application of the Code, Annex II.13 is repealed as of the date of entry into force of a corresponding regulation adopted pursuant to Article 17, paragraph 3, of Law No. 23 August 1988. 400, by decree of the Minister of Infrastructure and Transport, in agreement with the Minister of the Environment and Energy Security and the Minister for European Affairs, which replaces it in its entirety, also as an annex to the Code.*

*Article 117, paragraph 14, also provides that "For contracts to be performed by economic operators of proven solidity, as well as for the supply of goods that, due to their nature or the specific use for which they are intended, must be purchased at the place of production or supplied directly by the manufacturers, or for the supply of works of art, machinery, instruments, and precision work whose execution must be entrusted to specialized operators, exemption from the provision of the guarantee is possible upon adequate justification and is subject to an improvement in the award price or the performance conditions."*

#### **ART. 10 - GENERAL RESPONSIBILITIES OF THE SUPPLIER COMPANY**

In performing the supply, the Company shall, on its own initiative, adopt all means and precautions necessary to prevent damage in general, especially injuries, including to third parties.

The Company also undertakes to comply, under its sole responsibility, with all regulations regarding occupational health and safety and, in general, regarding the treatment and protection of workers. The Company declares and acknowledges that it fulfills all obligations set forth in Legislative Decree No. 81 of 9 April 2008, as amended, and in all other applicable regulations regarding occupational health and safety. The specific requirements to be observed in compliance with the applicable regulations in the context of the Covid-19 health emergency and related instructions provided by OPBG remain unaffected.

The Company itself is fully responsible for the exact fulfillment of the contractual conditions and the correct execution of the supply, it being explicitly understood that the rules and provisions contained in the contractual documents have been examined by it and recognized as suitable for achieving these purposes.

The Company is responsible for any damage or injury caused to structures or persons with which it comes into contact, at the locations of the supply, as a result of wilful or negligent conduct in the performance of the services covered by these Specifications, as well as wilful or negligent acts by its employees, collaborators, assistants in general, and anyone it uses in the fulfillment of its contractual obligations.

The Company will also be responsible for all consequences of any accidents and injuries that may occur to its personnel or property during the performance of the supply.

Furthermore, in all cases in which it accesses OPBG sites, the Company declares and acknowledges that OPBG has provided detailed information on the specific risks existing in the environments to which the Supplier's personnel have access in the performance of the Contract and on the prevention and emergency measures adopted in relation to the related activities. The Company undertakes to use the equipment and to acquire the necessary collective and personal protective equipment and to use them in accordance with applicable legislation and the Hospital's internal regulations.

To access and remain at OPBG, Company personnel are required to present an identification card with a photograph and containing the employee's personal details and the name of the employer. The foregoing is without prejudice to the Company's obligation to inform the Hospital of the names of those responsible for such personnel.

OPBG acknowledges that the internal contact is also the person appointed by the Hospital to promote cooperation and coordination with the supplier pursuant to Article 26 of Legislative Decree No. 81 of 9 April 2008, as amended.

#### **ART. 11 - SPECIAL COSTS FOR THE SUPPLIER COMPANY**

The Company shall bear the following special costs:

- a) The Company shall not request advance payments.
- b) The Company shall not request additional payments.
- c) The Company shall assume all civil and criminal liability arising from the performance of the supply in question, simultaneously relieving OPBG of all liability.

#### **ART. 12 - GENERAL OBLIGATIONS AND OBLIGATIONS OF THE SUPPLIER COMPANY**

The Company shall be responsible for the following obligations and obligations:

- a) delivery of the goods specified in these Specifications;
- b) compensation to OPBG for any damage to property or persons caused by the Company or its personnel;
- c) compliance with all obligations towards its employees pursuant to applicable laws, regulations, and the relevant collective bargaining agreement (CCNL) regarding labor and social insurance, assuming all related costs and excluding any liability for OPBG.

The Company therefore undertakes, through the organization of resources and management at its own and exclusive risk, the completion of all matters related to the supply covered by the Contract, guaranteeing that the same is performed in compliance with all provisions of the Contract and applicable legislation, and therefore also in a workmanlike manner or free from defects or faults. In this context, the Company also remains responsible for fulfilling all obligations related to environmental legislation and to such Fee the Company hereby acknowledges that it possesses all

necessary qualifications and authorizations and hereby undertakes to maintain them in compliance with said regulations for the entire term of the Contract.

The Company undertakes to guarantee and fulfill, at its own expense, all obligations towards personnel employed in connection with the Contract, as arising from applicable legislation, including those relating to insurance, social security, and employment relationships in general. In this regard, it shall provide a copy of the valid electronic DURC (certificate of retirement benefits) and documentation certifying the transmission of contribution data to INPS in the forms required by law. The Company also guarantees that all personnel employed by it possess all necessary qualifications to perform the services referred to in the Contract and further undertakes to communicate in advance to the OPBG Internal Contact the names of the personnel authorized by the Supplier to access the OPBG websites for this purpose.

The Company undertakes to perform the services set forth in the Contract without causing any harm to the Hospital's operations, also in light of the Hospital's unique research and treatment activities.

The Company unconditionally guarantees OPBG for all matters set forth above and further undertakes to indemnify and hold the Hospital harmless from any harm or damage, including damage to its reputation, that may arise from any fact, event, or circumstance directly or indirectly attributable to the Company through fraud or negligence, including personnel employed in connection with the Contract. The foregoing shall also apply in court proceedings and with respect to any third-party claims against OPBG, including Company personnel.

#### **ART. 13 - FORCE MAJEURE**

Neither Party shall be liable for failure to fulfill its contractual obligations when force majeure occurs, i.e., circumstances beyond its reasonable control.

#### **ART. 14 – CONTRACTUAL EXPENSES**

The contract and all related and consequent transactions are subject to the standard applicable taxes, duties, and duties. It is understood that all taxes, duties, and duties, stamp duty, and registration fees related to the registration of the Contract (if applicable) shall be borne by the Company.

#### **ART. 15 - DISPUTES AND LEGAL DOMICILE**

The Contract shall be governed by the law in force in the Italian State.

For any dispute arising from the interpretation and performance of the Contract, the Parties preliminarily undertake to resolve any conflict amicably. Only if an agreement cannot be reached, the Parties expressly agree to accept the exclusive jurisdiction of the Court of Rome and subsequent instances.

#### **ART. 16 – SUPPLY VARIATIONS**

If, during the performance of this contract, it becomes necessary to increase or decrease the scope of supply, the Company is obligated to execute the variation request with reference to the unit prices indicated in the financial quotation. Such variations may be requested for a value that cannot exceed one-fifth of the contractual amount.

#### **ART. 17 – PROCESSING OF PERSONAL DATA**

The Parties declare that they will comply with the provisions on the protection of personal data set forth in European Regulation No. 2016/679 (hereinafter "GDPR") and Legislative Decree No. 196/2003, as amended by Legislative Decree No. 101/2018, and will fulfill the resulting obligations by adopting appropriate technical and organizational measures to ensure a level of security appropriate to the risk.

The personal data of employees, collaborators, and any person acting in the name and on behalf of each Party (name, company email address, etc.) will be processed by the other Party, as an independent Data Controller, solely for purposes strictly related to and functional to the establishment and execution of the contractual relationship governed by this Agreement, as well as to fulfill any legal or regulatory obligations.

The data will be processed in compliance with the principles set forth in Art. 5, par. 1 of the GDPR, in the manner further described in the information pursuant to Art. 13 of the GDPR that each Party provides to its data subjects and for the period of time strictly necessary to achieve the purposes described above.

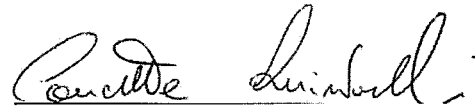
The Parties guarantee that the internal individuals involved in data processing are specifically authorized, trained, and instructed to ensure the adequate security and confidentiality of the personal data processed.

#### **ART. 18 - CONFIDENTIALITY PROVISIONS**

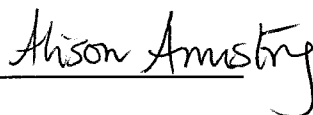
The Parties expressly agree that all information, concepts, ideas, procedures, methods, and/or technical data that the Company's personnel will become aware of during the supply process shall be considered confidential and protected by secrecy.

The Company is obligated to maintain the confidentiality of all data and information, including that transmitted through the equipment it possesses, and not to disclose it in any way or form, nor to use it for any purpose other than those strictly necessary for the performance of the contracted activities.

The Sole Project Manager  
Professor Concetta Quintarelli



For acceptance  
**BioReliance Ltd.**



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Bambino Gesù  
Ospedale Pediatrico  
Istituto di Ricovero e Cura  
a Carattere Scientifico



Organization Accredited  
by Joint Commission International

Rome, \_\_\_\_\_