

## **SPECIFICATIONS**

### **ACTIVATION OF ANALYTICAL SERVICES FOR THE RELEASE OF N. 2 “MASTER CELL BANKS” (MCB) AND N. 3 RETROVIRAL VECTORS TO BE USED AS “STARTING MATERIALS” IN THE PRODUCTION OF CAR-T DRUGS**

**CUP: E83C22003170001**

#### **ART. 1 - NATURE OF THE SUPPLY**

Negotiated procedure without prior publication of a tender notice pursuant to art. 76, paragraph 4, letter a), of Legislative Decree 36/2023, concerning the activation of analytical services for the release of n. 2 “master cell banks” (mcb) and n. 3 retroviral vectors to be used as “starting materials” in the production of car-t drugs.

For anything not expressly provided for in the cited sources, reference is made to the provisions of the Civil Code and to all the legal provisions in force on the matter.

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

The contractual relationship, relating to the negotiated 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 the agreements entered into between the “Bambino Gesù” Pediatric Hospital (“OPBG”) and **BioReliance Ltd.** (hereinafter Company or Supplier):

- Invitation letter;
- Technical Specifications;
- Response to Letter of Invitation with Financial Offer;
- ESPD;
- Contract.

The Hospital reserves the right to verify possession of the general requirements referred to in the declarations made by the Supplier.

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

The purpose of this Specification is to activate analytical services for the release of n. 2 “master cell banks” (mcb) and n. 3 retroviral vectors to be used as “starting materials” in the production of CAR-T drugs, as reported in the “Technical Specifications”.

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

The total estimated amount of this supply will be that offered by the Company, in any case not exceeding Euro 1.250.000.00 (one million two hundred and fifty thousand/00), plus VAT, where applicable, and will not be subject to variation.

#### **ART. 5 – PLACE OF SUPPLY**

This supply must be delivered to the OPBG Pharmaceutical Factory, Viale F. Baldelli, 38, 00146 Rome, within 5 months from the date of receipt of the order, without any additional charge for OPBG.

The Company undertakes to deliver all the above supplies, without any additional charge, safeguarding the needs of OPBG, without causing obstacles, disturbances or interruptions to any work activity in progress.

Furthermore, the Company waives any claim or request for compensation in the event that delivery should be hindered or made more expensive by the activities carried out by OPBG and/or third parties.

The resources responsible for delivering the supply to be carried out at OPBG will be able to access it in compliance with all the relevant safety and access requirements.

The Company, therefore, must guarantee that it has trained the technical personnel who will carry out the aforementioned services in order to protect the relevant safety.

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

#### **ART. 6 - PENALTY FOR LATE**

For each day of delay in the delivery of the supply in question with respect to the terms set out in the previous article 5 of this Specification, a penalty equal to 1% of the value of the supply itself 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 actions to compensate for any damages arising from the total or partial execution of the supply.

#### **ART. 7 - PAYMENT**

The Company will issue invoices for the consideration after delivery and compliance checks of the supply in question by OPBG.

In the event of a negative outcome of the aforementioned compliance checks, the invoice cannot be issued, unless the negative outcome is attributable to OPBG itself.

Invoices must:

- (i) report the references to the Contract and the related Execution Orders;
- (ii) contain, at the bottom, the words "Invoice bearing a non-transferable credit";
- (iii) indicate the reference bank details of the Supplier functional to the payment by OPBG;
- (iv) indicate the reference CUP code E83C22003170001

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

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

The sending of electronic invoices must be accompanied by a copy in "pdf" format of the invoices themselves and the necessary explanatory technical documents and free of sensitive and particular data in accordance with the applicable legislation on data protection.

Payment of invoices will be made by OPBG 90 (ninety) days from the end of the month from the invoice date.

Invoices will be paid following verification of contribution regularity by acquiring the DURC declaration.

Any errors, incompleteness, omissions of the data reported in the invoices pursuant to the foregoing or inconsistency of the explanatory technical documents as well as non-correspondence to current legislation, determine the rejection of the invoices by OPBG which therefore will not be able to proceed with the payment and consequently not will be required to recognize any late payment interest requested by the Company.

#### **ART. 8 – WARRANTY**

Pursuant to article 117 of Legislative Decree no. 36/2023 and subsequent amendments, for the signing of the contract the supplying company must constitute a guarantee, called "definitive guarantee" at its choice in the form of a deposit or surety with the methods of referred to in article 106, paragraphs 2 and 3, equal to 10 percent of the contractual amount. This deposit must be made up of public debt securities guaranteed by the State or with a bank guarantee or insurance policy or, also, in cash at the banking institution chosen by the Company.

Pursuant to paragraph 8 of the art. 106 *"The amount of the guarantee and its possible renewal is reduced by 30 percent for economic operators to whom it is issued, by accredited bodies, in accordance with the European standards of the UNI CEI EN 45000 series and the UNI CEI EN ISO/IEC 17000, the quality system certification compliant with the European standards of the UNI CEI ISO 9000 series. The 50 percent reduction, which cannot be cumulated with that referred to in the first period, applies to micro, small and medium-sized enterprises and groupings of economic operators or ordinary consortia made up 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 periods, when the economic operator presents a guarantee, issued and signed digitally, which is managed through the use of platforms operating with technologies based on distributed registers pursuant to paragraph 3. The amount of the guarantee and its possible renewal is reduced up to a maximum amount of 20 percent, cumulative with the reductions referred to in the first and second periods, when the economic operator possesses one or more of the certifications or brands 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 cumulative 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 reports, at the time of the offer, possession of the relevant requirements and documents it in the ways prescribed by the regulations in force. Upon first application of the code, Annex II.13 is repealed from the date of entry into force of a corresponding regulation adopted pursuant to Article 17, paragraph 3, of Law no. of 23 August 1988. 400, with 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 entirely also as an annex to the code".*

*It is also provided, pursuant to paragraph 14 of article 117 that "For contracts to be carried out by economic operators of proven solidity as well as for the supply of goods which due to their nature, or the special use for which they are intended, must be purchased in the place of production or supplied directly by the producers, or for the supply of art products, machinery, instruments and precision work, the execution of which must be entrusted to specialized operators, exemption from the provision of the guarantee is possible subject to adequate justification and is subject to an improvement in the award price or in the execution conditions".*

#### **ART. 9 - GENERAL RESPONSIBILITIES OF THE SUPPLIER COMPANY**

In carrying out the supply, the Company must adopt, on its own initiative, all those means and precautions that are effective in preventing damage in general and especially accidents, including to third parties.

The Company also undertakes to respect, under its sole responsibility, all regulations regarding safety and hygiene at work and in general regarding the treatment and protection of workers.

The Company declares and acknowledges that it fulfills all the obligations established by the Legislative Decree of 9 April 2008 n. 81 and subsequent amendments and additions and further applicable legislation on health and safety at work. The specific obligations to be observed in compliance with the applicable legislation in the context generated by the Covid-19 epidemiological emergency and related instructions provided by OPBG remain unaffected.

The Company itself is responsible for all purposes 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.

This Company is responsible for any damage or injury caused to structures or people with which it comes into contact, locations of supply, as a result of malicious or negligent behavior in the execution of the services covered by these Specifications as well as malicious or negligent actions of its employees, its collaborators, its auxiliaries in general and anyone it uses to fulfill its contractual obligations.

Likewise, the Company will be responsible for all the consequences of any accidents and accidents that may occur to its personnel or property during the execution of the supply.

Furthermore, for all cases in which it must access OPBG's 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 execution of the Contract and on the prevention and emergency measures adopted in relation to the related activity. The Company undertakes to use the equipment and to equip itself with the necessary collective and individual protective devices and use them in accordance with the applicable legislation and the internal regulations of the Hospital.

To access and stay at OPBG, Company personnel are required to show an identification card accompanied by a photograph and containing the worker's personal details and the indication

of the employer; the foregoing, without prejudice to the Company's obligation to indicate to the Hospital the names of those in charge with reference to said personnel.

OPBG acknowledges that the internal contact person is also the Manager identified by the Hospital to promote cooperation and coordination with the supplier pursuant to the provisions of the art. 26 of Legislative Decree 9 April 2008 n.81 and subsequent amendments and additions.

#### **ART. 10 - SPECIAL CHARGES FOR THE SUPPLIER COMPANY**

The following special charges are borne by the Company:

- a) No request by the Company for advance payments is permitted.
- b) No request by the Company for additional payments is permitted.
- c) The Company will assume all civil and criminal liability deriving from the execution of the supply in question, at the same time relieving the OPBG.

#### **ART. 11 - GENERAL OBLIGATIONS AND CHARGES BORNE BY THE SUPPLIER COMPANY**

The following obligations and charges are borne by the Company:

- a) the delivery of what is specified in these Specifications;
- b) compensation to OPBG for any damage to property or persons caused by the Company or by the personnel carrying out the work;
- c) compliance with all obligations towards its employees based on current legislative and regulatory provisions and the C.C.N.L. category in matters of employment and social insurance, assuming all the related costs with the exclusion of any liability for the OPBG.

The Company therefore assumes, with the organization of resources and management at its own and exclusive risk, the completion of everything related to the supply which is the subject of the Contract, guaranteeing that the same is made in compliance with all the provisions of the Contract and current legislation and therefore also workmanlike or free from faults or defects. In this context, the Company also remains responsible for the obligation to fulfill all obligations related to environmental legislation and in this regard the Company acknowledges that it is in possession of all the necessary requirements and authorizations and undertakes from now on to keep them compliant to said legislation for the entire validity of the Contract.

The Company undertakes to guarantee and satisfy, at its own expense and care, all obligations towards the personnel employed in connection with the Contract, as deriving from the applicable legislation, therein including that relating to insurance, social security and employment relationships in general and, in this context, to provide a copy of the valid electronic DURC, of the documentation certifying the transmission of the contribution data to the INPS in the legally required forms. The Company also guarantees that all the personnel employed by the same are in possession of all necessary qualifications to carry out the services referred to in the Contract and also undertakes to communicate in advance to the internal OPBG contact person the names of the personnel authorized for this purpose by the Supplier when accessing OPBG sites.

The Company undertakes to carry out the services referred to in the Contract without causing any prejudice to the activity of the Hospital, also in awareness of the peculiar research and treatment activity carried out by it.

The Company unconditionally guarantees OPBG for everything as provided above and also undertakes to indemnify and hold the Hospital harmless from any prejudice or damage, including to its image, which may arise from a fact or event or in any case circumstance to the Company itself directly or indirectly attributable to fraud or own fault including personnel employed in connection with the Contract; the foregoing is also valid in judicial proceedings and with reference to any claim by third parties against OPBG, such third parties also meaning personnel of the Company itself.

#### **ART. 12 - FORCE MAJEURE**

None of the Parties will be responsible for failing to fulfill their contractual obligations when there are causes of force majeure, i.e. circumstances beyond any reasonable control on their part.

#### **ART. 13 – CONTRACTUAL EXPENSES**

The contract and all related and consequent documents are subject to normal taxes, duties and duties in force. It is understood that all duties, taxes and duties, stamp duty and registration fees relating to the registration of the Contract (if used) are borne by the Company.

#### **ART. 14 - DISPUTES AND LEGAL DOMICILE**

The law in force in the Italian State applies to the Contract.

For any dispute arising from the interpretation and execution of the Contract, the Parties preliminarily undertake to settle any possible conflict amicably and, only in the impossibility of reaching an agreement, the Parties expressly agree to accept the exclusive jurisdiction of the Court of the Court of Rome and subsequent degrees.

#### **ART. 15 – SUPPLY CHANGES**

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

#### **ART. 16 – PERSONAL DATA PROCESSING**

The Parties declare to respect the provisions regarding the protection of personal data provided for in European Regulation no. 2016/679 (hereinafter “RGPD”) and in Legislative Decree no. 196/2003, as amended by Legislative Decree no. 101/2018, and to fulfill the resulting obligations, adopting the appropriate technical and organizational measures to guarantee a level of safety appropriate to the risk.

The personal data of employees, collaborators and in any case of any person who operates in the name and on behalf of each Party (name, company e-mail address, etc.), will be processed by the other Party, in its capacity as independent data controller, solely for purposes strictly related and functional to the establishment and execution of the contractual relationship governed by this Contract, as well as to fulfill any legal or regulatory obligations.

The data will be processed in compliance with the principles set out in art. 5, par. 1 of the GDPR, with the methods better described in the information pursuant to art. 13 of the GDPR that each

Party provides to its interested parties and for the period of time strictly necessary to achieve the purposes described above.

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

#### **ART. 17 - PROVISIONS FOR THE PROTECTION OF CONFIDENTIALITY**

It is expressly agreed between the Parties that all information, concepts, ideas, procedures, methods and/or technical data of which the personnel employed by the Company will become aware during the supply must be considered confidential and covered by secrecy.

The Company has the obligation to keep the data and information confidential, including that which passes through the equipment of which it comes into possession and not to disclose them in any way or in any form and not to make them subject to use in any capacity for purposes other than those strictly necessary for the execution of the activities covered by the contract.

The Sole Project Manager  
Dott.ssa Monica Gunetti



For acceptance  
**BioReliance Ltd.**

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