

Rome, 16/09/2025

Esteemed

BioReliance Ltd.

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SUBJECT: Letter of invitation to participate in the 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 - **CUP Code E83C22006230001.**

The “Bambino Gesù” Pediatric Hospital (hereinafter “OPBG”), with headquarters in Rome, Piazza S. Onofrio n. 4 - 00165 Rome, in the person of the RUP, Prof. Concetta Quintarelli, by virtue of an assignment received on 02/09/2025, Prot. n. 333/DG, with this letter of invitation pursuant to art. 89 of Legislative Decree 31 March 2023, n.36,

INVITE

this Economic Operator to participate in the tender procedure in question by submitting its best offer.

Article 1

Contact Points

1. The OPBG contact points are as follows:

- Sole Project Manager: Professor Concetta Quintarelli, tel. +39 06 6859 3962, email: concetta.quintarelli@opbg.net;
- Dr. Massimiliano Giaccio, Administrative Officer, tel. +39 06 6859 3631, email: massimiliano.giaccio@opbg.net;
- Dr. Monica Gunetti, Technical Officer, tel. +39 06 6859 7201, email: monica.gunetti@opbg.net;

Article 2

Tender Documentation

1. The tender documentation includes:

- a) Invitation letter;
- b) Technical specifications;
- c) Specifications;
- d) Acknowledgement of invitation letter with financial offer;
- e) DGUE (ESPD).

This invitation letter applies the specific principles and obligations of the PNRR regarding the avoidance of significant harm to the environmental objectives (Do No Significant Harm, pursuant to Article 17 of Regulation (EU) 2020/852) and, where applicable, cross-cutting principles, such as, among others, the principle of contributing to the climate and digital objectives (so-called "Tagging"), gender equality, the protection and valorization of young people, the overcoming of territorial divides, and the inclusion of persons with disabilities in the workplace.

Article 3

Participation Requirements

1. The Economic Operator must declare that it meets the general participation requirements by submitting the European Single Procurement Document (ESPD) and the application form referred to in Article 91 of Legislative Decree No. 36 of 31 March 2023, preferably using the forms made available by the OPBG.
2. Pursuant to Article 91 of Legislative Decree No. 36 of 31 March 2023, the OPBG may ask the Economic Operator, at any time during the procedure, to submit all or part of the additional documents, if this is necessary to ensure the proper conduct of the procedure.
3. Under penalty of exclusion, the Economic Operator must meet the following requirements:
 - a. the absence of the grounds for exclusion set forth in Articles 94 to 98 and Annex II.10 of Legislative Decree No. 36 of 31 March 2023;
 - b. absence of the causes of incompatibility referred to in Article 53, paragraph 16-ter, of Legislative Decree no. 165 of 30 March 2001, as amended (this cause for exclusion applies for the three years following the violation).
4. The Hospital reserves the right to verify possession of the general requirements referred to in the declarations made by the Supplier.
5. Since this procedure relates to investments financed with PNRR/PNC resources, the following is also specified:
 - a) The Economic Operator who employs more than fifty employees is excluded from the tender procedure, in the case of failure to produce, at the time of submission of the offer, a copy of the latest periodic report on the situation of male and female staff drawn up pursuant to the Article 46, Legislative Decree no. 198 of 2006, with certification of its conformity to that which may have already been sent to the company union representatives and the regional equality councilors or, failing that, with certification of its simultaneous transmission to the company union representatives and to the councilor and to the regional equality councilor.
 - b) The competitor undertakes, under penalty of exclusion, in the event of awarding the contract, to ensure: 1) a quota equal to 30 percent of youth employment; 2) a quota equal to 40 percent of female employment of the hires

necessary for the execution of the contract or for the implementation of activities connected or instrumental to it.

c) The Economic Operator employing a number of employees equal to or greater than fifteen and not exceeding fifty, who in the twelve months preceding the deadline for submitting the offer has failed to produce to the contracting authority of a previous procurement contract, financed in whole or in part with PNRR or PNC funds, the report referred to in article 47, paragraph 3 of Legislative Decree no. 77 of 2021.

Article 4

Presentation of tender documents

1. This Economic Operator must send, in the manner referred to in the following paragraph, all the tender documents referred to in article 2, in electronic format signed by the Legal Representative or by an Attorney with digital signature referred to in the art. 1, paragraph 1, letter s), of Legislative Decree no. 82/2005. The document referred to in article 2, letter d) must be completed on headed paper. The document referred to in article 2 letter e) must be completed by the Economic Operator.

2. The tender documents must be received no later than the peremptory deadline **of 12:00 on 30/09/2025**, to the following addresses: roberto.dipinto@opbg.net - giacomo.disalvo@opbg.net, under penalty of inadmissibility of the same and non-admission to the procedure in question.

DR. Christians Hill

The Sole Project Manager

Professor Concetta Quintarelli

