

Rome, 02/07/2025

Prot. n. 113/PR

CHILDREN'S HOSPITAL BAMBINO GESU' THE PRESIDENT

HAVING SEEN Legislative Decree no. 36 of 31 March 2023 and subsequent amendments (hereinafter "Public Contracts Code") and subsequent amendments;

HAVING SEEN the Presidential Decree of 5 October 2010, no. 207, as currently in force, which regulates the execution and implementation of the Public Contracts Code;

HAVING SEEN ANAC guidelines no. 8 concerning the "Recourse to negotiated procedures without prior publication of a tender notice in the case of supplies and services deemed non-fungible" adopted with resolution no. 950 of 13 September 2017;

HAVING SEEN the Public Notice of 20/02/2025 in both Italian and English, published on the Hospital Portal, for the preliminary market consultation preparatory to the announcement of a procedure for the awarding of the supply 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, with respect to which only the Company Bioreliance Ltd. expressed its interest in participating in the tender procedure in question and the OPBG accepted this expression, following technical assessments carried out by the competent internal Function;

HAVING SEEN the letter of clarification dated 02/24/2025 in both Italian and English, published on the Hospital Portal and signed by the Manager of the Legal Function, containing the following wording: "*.....We hereby communicate that, with reference to the "PUBLIC NOTICE FOR THE PRELIMINARY MARKET*

CONSULTATION PRELIMINARY TO THE CALL FOR A PROCEDURE FOR THE AWARDING OF THE SUPPLY OF NO. 2 “MASTER CELL BANKS” (MCB) AND NO. 3 RETROVIRAL VECTORS TO BE USED AS “STARTING MATERIALS” IN THE PRODUCTION OF CAR-T DRUGS. – CUP E83C22003170001” signed on 02/20/2025, also drafted in English, due to a mere material typo, the aforementioned title is replaced with the following: **“PUBLIC NOTICE FOR THE PRELIMINARY MARKET CONSULTATION PRELIMINARY TO THE CALL FOR A PROCEDURE FOR THE ACTIVATION OF ANALYTICAL SERVICES FOR THE RELEASE OF NO. 2 “MASTER CELL BANKS” (MCB) AND NO. 3 RETROVIRAL VECTORS TO BE USED AS “STARTING MATERIALS” IN THE PRODUCTION OF CAR-T DRUGS. – CUP E83C22003170001”** at the Pharmaceutical Factory of the Bambino Gesù Pediatric Hospital. With the exception of the above, all the contents of the public notice of 02/20/2025, reported in the same letter of clarification of 02/24/2025, remain unchanged”;

HAVING SEEN the determination to contract no. 58 prot. no. 61/PR of 10/03/2025, the premises of which are hereby deemed to be fully recalled, with which the President of the Bambino Gesù Pediatric Hospital (“OPBG”) has authorized the start of the negotiated procedure without prior publication of a tender notice pursuant to art. 76, paragraph 4, letter a) of the Public Contracts Code, intended for the activation of analytical services for the release of no. 2 “Master Cell Banks” (MCB) and no. 3 Retroviral Vectors to be used as “Starting Materials” in the production of Car-T drugs. - CUP E83C22003170001. The activation of the analytical services mentioned above is provided by BioReliance Ltd for a discounted amount equal to Euro 1,052,698.20 (one million fifty-two thousand six hundred ninety-eight/20) plus VAT, where applicable, compared to the maximum supply amount equal to Euro 1,250,000.00 (one million two hundred fifty thousand/00), plus VAT, where applicable, reported in the Determination to contract, simultaneously appointing Dr.

Monica Gunetti as The Sole Project Manager, pursuant to Article 15 of the Public Contracts Code;

HAVING SEEN the transmission on 17/04/2025 by the OPBG to the economic operator BioReliance Ltd of the invitation letter with the related attachments, indicating 18:00 on 05/05/2025 as the deadline for participation in the tender procedure in question;

HAVING SEEN the response to the invitation letter sent by BioReliance Ltd with offer R-10455064.P.1, accompanied by all the required documentation digitally signed;

HAVING SEEN the letter of clarification dated 10/06/2025 submitted by OPBG in both Italian and English, through which BioReliance Ltd was asked to reformulate offer no. R-10455064.P.1 with the inclusion of the CUP Code E83C22003170001 of the procurement procedure in question and the justifications were provided which led to an update of the Technical Specifications attached to the public notice for the preliminary market consultation preparatory to the announcement of a procedure for the activation of analytical services for the release of no. 2 “Master Cell Banks” (mcb) and no. 3 Retroviral Vectors to be used as “Starting Materials” in the production of Car-T drugs;

HAVING SEEN the response to the letter of clarification provided by BioReliance Ltd dated 20/06/2025, by formulating an updated economic offer, offer no. R-10455064.P.4, and corresponding to the requests of the OPBG;

HAVING SEEN the evaluation document dated 06/23/2025 with which the proposed technical offer no. R-10455064.P.4 was examined;

HAVING SEEN the evaluation document dated 06/23/2025, with which the economic offer no. R-10455064.P.4 was deemed appropriate for the discounted amount of Euro 1,052,698.20 (one million fifty-two thousand six hundred ninety-eight/20) plus VAT, where applicable, compared to the maximum amount of the

supply of Euro 1,250,000.00 (one million two hundred fifty thousand/00), plus VAT, where applicable, reported in the Determination to contract;

WHEREAS the OPBG has initiated the verification of the prescribed requirements in relation to BioReliance Ltd;

CONSIDERING that it is necessary to proceed with the awarding of the above-mentioned tender on the basis of the documents and documentation produced, necessary for the stipulation of the contract;

CONSIDERING that, as provided for by Article 17, paragraph 5 of the Public Contracts Code, the award becomes effective after the positive verification of the possession of the required requirements, as well as the constitution of the definitive guarantee referred to in Article 8 of the Contract Specifications;

HAVING SEEN the CUP Code E83C22003170001 assigned by the Ministry of Economy and Finance;

All of the above having been seen, considered and stated, which constitutes an integral part of this provision

ARRANGE

1. to award to the company **BioReliance Ltd** with registered office in Glasgow, Scotland, at Unit 5, Todd Campus, West of Scotland Science Park, G20 0XA, Tax Code 6805014990 / VAT number GB 845 3370 24, the negotiated procedure without prior publication of a tender notice pursuant to art. 76, paragraph 4, letter a), of Legislative Decree 31 March 2023, no. 36 identified by CUP E83C22003170001, for the activation of analytical services for the release of no. 2 “Master Cell Banks” (MCB) and no. 3 Retroviral Vectors to be used as “Starting Materials” in the production of Car-T drugs. - CUP E83C22003170001, for an amount including the

applied discount equal to **Euro 1,052,698.20 (one million fifty-two thousand six hundred and ninety-eight/20) plus VAT, where applicable;**

2. that the aforementioned award becomes effective only following the activation of the definitive guarantee constituted by BioReliance Ltd, pursuant to art. 117 of Legislative Decree 36/2023, in the forms provided for by art. 106 of Legislative Decree 36/2023, as provided for in art. 8 of the Contract Specifications, within 10 days of the signing of this award decree;

3. that the aforementioned award becomes effective only following the positive outcome of the checks required by the legislation in force on participation requirements;

4. that, following the checks provided for in points 2 and 3, the necessary formalisation of the contract will follow;

5. to advertise the award using the methods provided by law.

The President
Tiziano Onesti

