Rome, 24/02/2025

We inform you that, with reference to the **"PUBLIC NOTICE FOR THE PRELIMINARY MARKET CONSULTATION IN PREPARATION FOR THE INDICATION 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 DRUG CAR-T. – CUP E83C22003170001"** signed on 02/20/2025, also written in English, for a mere typo of a material nature, the aforementioned title is replaced with the following: **"PUBLIC NOTICE FOR THE PRELIMINARY MARKET CONSULTATION PREPARATORY FOR THE INDICATION OF A PROCEDURE FOR THE ACTIVATION OF ANALYTICAL SERVICES FOR 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"** at the Pharmaceutical Workshop of the Bambino Gesù Pediatric Hospital.

With the exception of the above, the entire content of the public notice dated 02/20/2025 referred to remains unchanged and is reported in full below:

The "Ospedale Pediatrico Bambino Gesù" (hereinafter, for brevity "**contracting authority**") announces that, for the preparation of the contract and for the carrying out of the related procedure relating to the supply of the services in question, it intends to carry out a specific preliminary market consultation pursuant to the articles 77 and 78 of the Legislative Decree. n. 36/2023.

The contracting authority therefore invites all interested parties to participate in the "consultation" by providing the contributions deemed necessary. In particular, the aspects governed by the documentation attached to this notice are the subject of the contribution.

It will be the responsibility of the subjects interested in this notice to highlight the contributions for which they reasonably believe there are aspects worthy of protection of secrecy from a technical and commercial point of view.

It is represented that:

- the needs and the tools to meet them can be found in the attached documentation;

- the indicative total cost for the acquisition of the supply and services can be estimated approximately at an amount equal to € 1.250.000,00 excluding VAT;

- the contracting authority will evaluate any reasonable alternative solutions proposed in the context of the contributions provided;

- the contracting authority will proceed with the purchase through a procedure that will be identified pursuant to Legislative Decree. n. 36/2023, if at the end of the investigation it finds the existence of the relevant conditions and therefore does not consider any reasonable alternative solutions proposed to be viable.

- finally, the contracting authority remains available to provide further information that economic operators may request in compliance with the principles of transparency and equal conditions.

Participation in this "*consultation*" does not give rise to any expectations or rights towards the contracting authority and the contributions made do not give the right to any compensation or reimbursement. The assignment of the supply covered by this "*consultation*" is subject to any subsequent and separate procedure carried out pursuant to and for the purposes of the Legislative Decree. 36/2023.

This "*consultation*" does not, therefore, represent an invitation to propose an offer, nor does it bind the contracting authority in any way towards the interested parties.

The contracting authority may at its sole discretion interrupt, suspend or revoke this "*consultation*", as well as interrupt the consultation of one or more of the interested parties, at any time.

The contracting authority reserves the right to use what is collected as part of this "*consultation*" for the planning and carrying out of the procurement procedure, "*provided that it does not have the effect of distorting competition and does not lead to a violation of the principles of discrimination and transparency*" (art. 77, paragraph 2, Legislative Decree no. 36/2023).

The form of the contributions is free (it is preferable that the files consist of electronic documents rather than scans of paper documents) and may include the documentation referred to in the art. 77 paragraph 2 of the Legislative Decree. n.36/2023.

Contributions must be received by 28/02/2025 to the addresses roberto.dipinto@opbg.net and giacomo.disalvo@opbg.net. The email must contain the following wording in the subject: *"PUBLIC NOTICE FOR THE PRELIMINARY MARKET CONSULTATION IN PREPARATION TO THE INDICATION OF A PROCEDURE FOR 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. - sending contribution" - CUP E83C22003170001.* The contracting authority will not take into consideration contributions that are not submitted in the manner described and within the deadline indicated.

For any further information relating to the methods of participation in this consultation, it is possible to use the aforementioned electronic address (for information of an administrative nature and for information relating to the technical specifications and other elements of a technical/economic nature).

The Manager of the Legal Function

TECHNICAL DOCUMENT PRELIMINARY CONSULTATION

1) REQUIREMENT

The activation of analytical services is requested 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 better specified in the Technical Specifications. The analyzes to be carried out are aimed at confirming identity, verifying virological and microbiological safety of use and evaluating impurities in the materials being released and are complementary to further analyzes carried out at the Officina Farmaceutica of the OPBG.

2) EXPECTED COSTS

The expected costs for the supply and services in question are estimated at an amount equal to 1.250.000,00 Euros (excluding VAT).

Bambino Gesù
OSPEDALE PEDIATRICO

Exhibit 1

Technical Specifications for the Release Analysis of "Master Cell Banks" and Retroviral Vectors

The Bambino Gesù Paediatric Hospital (OPBG) requires 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. The analyses to be carried out are aimed at confirming identity, verifying virological and microbiological safety, and evaluating impurities in the materials subject to release. These analyses are complementary to additional tests carried out at the Officina Farmaceutica of the OPBG. For the release of retroviral vectors, both the vectors themselves and the collection of producer cells after the production of the vectors, known as "Post Production Cell Bank" (PPCB), are analyzed. Tables 1 and 2 respectively list the denominations of the required analyses for the two MCBs and the three retroviral vectors to be released.

Tabella 1. Required assays for MCB release (n=2).

Saggio		**#**
MCB (HEK Vec 293 RD114) identity	DNA Fingerprinting by STR Assay	x2
Microbiological evaluation	Sterility EP 2.6.1	x2
	Bacteriostasis (Sterility validation EP 2.6.1.)	x2
	LAL Validation and test	x2
	Detection of mycoplasma by culture and staining EP 2.6.7	x2
	Detection mycoplasma by culture (EP 2.6.7)	x2
Virological evaluation	Determination of viral contaminants (*in vitro*) using cell lines according to EMA/CHMP/ICH/804363/2022	x2
	Detection of porcine viruses using Vero and PPK cell lines according to 9CFR guideline and EP	x2
	Detection of bovine viruses using Vero and BT cell lines according to 9CFR guideline and EP	x2
	In vivo adventitious agent detection using embryonated hen eggs, suckling and adult mice	x2
	Quantitative PCR for HIV-1, HIV-2, HTLV 1&2, EBV, HCMV, HHV6, HHV7, HHV8, HAV, HBV, HCV, PCV1 (DNA), PCV2 or BCV(DNA), SV40	x2
	h. polyomavirus JC and BK sequences	x2
	h. papillomavirus	x2
	h. enterovirus	x2
	PCV1 (DNA), PCV2, BCV(DNA)	x2
Impurities evaluation	Assay for RD114 retrovirus Detection (Supernatant) (FDA-1999-D-0081) with GaIV and RD114 as positive controls (with GaIV and/or RD114 titration, if necessary)	x2
	Assay for RD114 retrovirus Detection (Cells) (FDA-1999-D-0081) with GaIV and RD114 as positive controls (with GaIV and/or RD114 titration, if necessary)	x2
	Detection of contaminanting agents by TEM	x2

Tabella 2. Required assays for viral vector release (n=3).

Saggi su PPCB		#
PPCB (HEK Vec 293 RD114) identity	DNA Fingerprinting by STR Assay	x3
Microbiological evaluation	Detection of mycoplasma by culture and staining EP 2.6.7	x3
	Detection mycoplasma by culture (EP 2.6.7)	x3
Virological evaluation	Determination of viral contaminants (*in vitro*) using cell lines according to EMA/CHMP/ICH/804363/2022	x3
	Detection of porcine viruses using Vero and PPK cell lines according to 9CFR guideline and EP	x3
	Detection of bovine viruses using Vero and BT cell lines according to 9CFR guideline and EP	x3
	In vivo adventitious agent detection using embryonated hen eggs, suckling and adult mice	x3
Impuritiy evaluation	Assay for RD114 retrovirus Detection (Supernatant) (FDA-1999-D-0081) with RD114 as positive control (with RD114 titration, if necessary)	x3
	Assay for RD114 retrovirus Detection (Cells) (FDA-1999-D-0081) with RD114 as positive control (with RD114 titration, if necessary)	x3
Saggi su vettore retrovirale		#
Microbiological evaluation	Detection mycoplasma by culture (EP 2.6.7)	x3
	Validation of mycoplasma	x3
Virological evaluation	Determination of viral contaminants (in vitro) using cell lines according to EMA/CHMP/ICH/804363/2022	x3
	Detection of porcine viruses according to 9CFR guideline and EP	x3
	Detection of bovine viruses according to 9CFR guideline and EP	x3
	Assay for RD114 retrovirus Detection (Supernatant) (FDA-1999-D-0081)	x3
	In vivo adventitious agent detection using embryonated hen eggs, suckling mice and adult mice (ICH Q5a, PCT 1993)	x3
Impuritiy evaluation	Host cell DNA (E1B, E1A)	x3
	Osmolality	x3