NRRP Mission 4, Component 2, Investment 1.4 "Strengthening of research facilities and creation of "national R&D champions" on some Key Enabling Technologies"
Initiative funded by the European Union –- NextGenerationEU.
National Center for Gene Therapy and Drugs based on RNA Technology
RNA Gene Therapy and Drug Development
Project code MUR: CN00000041 – CUP UNINA: E63C22000940007

DEED OF COMMITMENT

Open procedure with the application of the criterion of the most economically advantageous offer identified on the basis of the best value for money, pursuant to art. 71 and 108 paragraph 1 of Legislative Decree no. 36/2023 as amended, concerning the supply of an "Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System – Lot 1; " Automated System for GMP mRNA production at scale for clinical stages and commercial production with Critical – Lot 2".

The undersigned _____[indicate personal details], Tax Code _____, representing the economic operator (name and legal form) _____ _____ participant (hereinafter "Competitor") in the procedure opened pursuant to art. 71 and 108 of D.L.gs no. 36/2023, as part of the Project**:** PNRR Mission 4, Component 2, Investment 1.4 "*Strengthening research facilities and creating 'national R&D champions' on some Key Enabling Technologies*" Initiative funded by the European Union - NextGenerationEU. National Center for Gene Therapy and Drugs based on RNA Technology Development of gene therapy and drugs with RNA technology MUR project code: CN00000041 – CUP E63C22000940007

Whereas:

- Public Notice no. 3138 of 16 December 2021 of the MUR, partially amended by Directorial Decree no. 3175 of 18 December 2021, relating to the submission of Proposals for the Strengthening of research facilities and creation of "national champions" of R&D on certain Key Enabling Technologies to be funded under the PNRR Mission 4, "Education and Research" – Component 2, "From Research to Enterprise" – Investment Line 1.4 "Strengthening research facilities and creating 'national R&D champions' on selected Key Enabling Technologies", funded by the European Union – NextGenerationEU;
- in response to the aforementioned Public Notice, the project submitted by the University, submitted to the MUR and ratified by the Board of Directors with resolution no. 170 of 4 April 2022, with which the establishment of a Foundation - as the implementing entity (HUB) of the Research Programme - between the University and state and public research bodies supervised by the MUR and with the involvement of non-state universities, other public research bodies and other public or private entities, highly qualified in the research topic covered by the CN, providing for a total cost of the project equal to € 400,000,000.00

and called National Center for Gene Therapy and Drugs based on RNA Technology" – marked with the identification code "CN00000041";

-with Directorial Decree no. 1035 of 17 July 2022, with which the MUR approved the final project and the plan of costs and benefits, establishing a total contribution of € 328,814,550.46 for the final project with a contribution to the expenditure of € 320,036,606.03;

- the "*National Center for Gene Therapy and Drugs based on RNA Technology*" project, which began on 1 September 2022 with a final deadline of 31 August 2025, with the possibility of extension to 28 February 2026, provides for a cost of € 27,974,916.65 for the University of Naples Federico II, fully covered by the contribution to the expenditure of € 320,036,606.03;

- The Department of Pharmacy of the University of Naples Federico II, as part of the scientific research activity of the CN00000041, National Center for Gene Therapy and Drugs based on RNA Technology Development of gene therapy and drugs with RNA technology, with a specific Milestone dedicated to the creation of an RNA plant for the GMP production of clinical batches of therapeutic mRNA, intends to purchase two automated mRNA production systems with critical reagent supply and processing system. This requires high-performance instrumentation capable of automatically synthesizing mRNA at scale suitable for drug discovery and preclinical development (batch 1) and a second automated system for the production of GMP mRNA at scale for clinical stages and commercial production (batch 2), which is essential to create a rational development pipeline. The mRNA production steps that must be performed automatically and with high repeatability are transcription from a DNA template, purification, and processing of the synthesized mRNA molecule to remove any contaminants and unwanted species. The final products must meet a high process yield and a high-quality profile

with the present Act

The operator identified in the epigraph expressly and irrevocably assumes all – without exception – the following constraints, charges and commitments and, therefore, declares, pursuant to art. 46 and 47 of D.P.R. no. 445/2000 and subsequent amendments, aware of the criminal sanctions referred to in art. Article 76 of that decree provides:

1. to have full knowledge of the Documentation attached to this tender procedure, and to accept and comply with all the provisions contained therein;
2. to undertake (if it employs a number equal to or greater than fifty employees and is required to draw up a report on the situation of personnel pursuant to Article 46 of Legislative Decree no. 198 of 11 April 2006), to produce, under penalty of exclusion, a copy of the last report drawn up, with certification of its compliance with the one sent to the company trade union representatives and to the director

or, in the event of non-compliance with the terms set out in paragraph 1 of the same Article 46, with certification of its simultaneous transmission to the company trade union representatives and to the regional equality councilor;

3. to undertake (if it employs a number equal to or greater than fifteen employees and not more than fifty and is not required to draw up a report on the situation of personnel, pursuant to Article 46 of Legislative

Decree No 198 of 11 April 2006) to deliver, within six months of the conclusion of the contract, a gender report on the situation of male and female staff in each of the professions and in relation to the state of recruitment, training, professional promotion, levels, changes in category or qualification, other mobility phenomena, the intervention of the Wage Guarantee Fund, dismissals, early retirements and retirements, remuneration actually, paid and to transmit the aforesaid to the company trade union representatives and to the regional equality councilor, under penalty of the application of the penalties referred to in Article 47, paragraph 6 of Decree-Law No. 77 of 31 May 2021, converted with amendments by Law No. 108 of 29 July 2021;

4. to undertake (if it employs fifteen or more employees) to deliver, within six months of the conclusion of the contract, a report clarifying the fulfilment of the obligations imposed on the undertakings by Law no. 68 of 12 March 1999, and illustrating any sanctions and measures imposed on the undertakings in the three years preceding the deadline for the submission of tenders. The economic operator is also required to send the report to the company's trade union representatives, under penalty of the application of the penalties referred to in art. 47, paragraph 6, of Decree-Law No. 77 of 31 May 2021, converted with amendments by Law No. 108 of 29 July 2021;

5. to undertake (in the event of the award of the tender procedure in its favor) to ensure:

- a quota equal to 30% of the recruitments necessary for the execution of the contract or for the implementation of activities related to it or instrumental to youth employment (under 36 years of age);
- a quota equal to 30% of the recruitment necessary for the execution of the contract or for the implementation of activities related to it or instrumental to the employment of women.

6. To commit to complying with the specific obligations of the NRRP, including the principle of not causing significant harm to the so-called environmental objectives. "Do No Significant Harm" (DNSH) pursuant to Article 17 of Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020, as well as with reference to the "Operational Guide" referred to in MEF Circular No. 22 of 14 May 2024.

The competitor also undertakes to provide, pursuant to MEF Decree no. 55 of 11 March 2022, the data necessary for the identification of the beneficial owner of the economic operator itself (referred to in Article 20 of Legislative Decree 231/2007).

The tenderer and the beneficial owner undertake to declare the absence of situations of conflict, even potential, of interests in relation to this procedure and to undertake, if such a situation should occur at a later time, to promptly notify the contracting authority.

_____the_____

SIGNATORY

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digitally signed