PNRR Mission 4, Component 2, Investment 1.4 "Strengthening of research and research facilities" 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 Development of gene therapy and drugs with RNA technology MUR project code: CN00000041 – CUP UNINA: E63C22000940007

UNIVERSITY OF NAPLES FEDERICO II

DEPARTMENT OF PHARMACY

TECHNICAL REPORT

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 and supplemented 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".
CUP: E63C22000940007 – WHICH: F00876220633202400035

Automated mRNA Production System at scale suitable for drug discovery and preclinical development with Critical Reagent Supply and Processing System

Essential technical requirements and characteristics:

- A fully automated piece of equipment suitable for non-GMP mRNA production at scale suitable for drug discovery and preclinical development.
- The equipment must be self-contained except for reagent placement including priming and calibration, disposables, product and sample collection, and waste removal.
- The automated system for mRNA production is expected to enable increased efficiency, performing mRNA synthesis and processing tasks much faster than manual methods, resulting in

higher productivity and throughput. This efficiency enables the rapid production of high amounts of mRNA, which is essential for applications such as vaccine development or high-throughput (HT) screening.

- The automated system for mRNA production is expected to enable improved accuracy and precision, reducing the risk of human error inherent in manual processes, resulting in more consistent and reproducible mRNA products. The system should allow precise control of reaction conditions, time and reagent volumes, reducing variability and ensuring the quality and integrity of mRNA molecules.
- The automated system for mRNA production should allow scalability, adapting to different production needs.
- The automated system for mRNA production should enable an optimized workflow, integrating multiple steps in the mRNA production process into a single platform and reducing the need for manual intervention. This integration should save time and minimize the risk of sample contamination and cross-contamination between samples.
- The automated system for mRNA production should enable in-line quality control, to ensure the quality and purity of the mRNA product. These quality control features should help identify and address any deviations from expected results in a timely manner, while maintaining product consistency and reliability.
- The automated system for mRNA production is expected to save resources by automating repetitive and intensive tasks, reducing the need for skilled labor and hours of manual labor, minimizing the consumption of expensive reagents and materials.
- The equipment must process 19.2 ml of IVT.
- The equipment must provide a well-defined sequence translation and purification step for

each IVT output.

- The overall size of the equipment must be kept to a minimum, and the system must be easily lifted for installation.
- The automated system for mRNA production should allow flexibility and customization, allowing users to tailor the mRNA production process to their specific needs (e.g., by introducing multiple DNA templates, preferably 48, for in vitro transcription of various RNA sequences in parallel and by producing at least 2 mg of mRNA for each DNA template).

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