CALL NOTICE N.º 002/2021

FUNDAÇÃO BUTANTAN, a private non-profit legal entity established on 31st May 1989 by means of a public deed duly registered at the 3rd Notary Public for Legal Entities of São Paulo-SP under number 133326, Taxpayer Registration number 61.189.445/0001-56, accredited as a Supporting Foundation of the Science and Technology Institution of the State of São Paulo (ICTESP) as per Resolution number 55/2018 of the Science, Technology and Economic Development Secretariat (SDECT) with headquarters at 1500, Avenida Vital Brasil, Butantã, São Paulo – SP, Brazil ZIP CODE 05503-900, hereby resolves:

TO PUBLICLY COMMUNICATE this **Public Call Notice** aims to set forth information on and to choose a company to be partner of IB on – 23-VALENT PNEUMOCOCCAL POLYSACCHARIDE VACCINE, through a Technology Transfer and Supply (License), whose procedure will take place in accordance with the provisions of this Notice.

1. **OBJECT**

Fundação Butantan calls, in order to receive proposals from any interested parties to participate in the IB – 23-VALENT PNEUMOCOCCAL POLYSACCHARIDE VACCINE, for the conclusion of a Technology Transfer and Supply Agreement, including the transfer of the bacteria strains master and work banks (23 VALENT), production technology , formulation, filling, packaging of the vaccine, according to each stage of the project and according to the needs of the Instituto Butantan, with the main objective of serving the public market.

23-VALENT PNEUMOCOCCAL POLYSACCHARIDE VACCINE, aims to prevent pneumococcal diseases caused by the 23 types of pneumococcal bacteria contained in the vaccine in question (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F).

2. **TOPICS AND REQUIREMENTS**

For discussion of the topic, this public call will address the following topics, which the interested parties and the vaccine (product) must, necessarily, have as requirements:

2.1 License of the product at the main regulatory agencies for medicines and health products, such as ANVISA (National Health Surveillance Agency), FDA (Food and

Drug Administration) and EMA (European Medicines Agency) and / or be pre-qualificated by the World Organization of Health (WHO) for that product. Those interested in the project must be holders of active license of the PNEUMOCOCCAL POLYSACCHARIDE VACCINE, with these agencies, and be able to transfer the license to the Instituto Butantan, if necessary.

2.2 Be able to supply at least 500.000 (five hundred thousand) doses, in finished product per year, of the vaccine. The quantity of vaccines for supply mentioned is based on the current demand from the public market and may undergo changes, such as the interruption or modification of the quantity supplied, or if the Instituto Butantan deems it necessary.

2.3 Interested parties must have a technological production platform compatible with established technological bases, such as production at fermenters, and / or that are compatible with the existing platforms at the Instituto Butantan, in order to enable the transfer of technology.

2.4 To participate in the project, interested parties should consider the possibility of transferring the bacteria strains master and work banks (23 valent), production technology, formulation, filling, packaging (this transfer being total or partial). The technology transfer will occur progressively in relation to the supply of the product and / or time of agreement, in other words, the greater the supply of the product and / or time of agreement, the more stages of the manufacturing process may be required for the technology transfer to the Instituto Butantan, as proposed in the table below.

TECHNOLOGY TRANSFER STEPS	SUPPLIED DOSES (Accumulated)	TIME (Accumulated)
Finished Product	500.000	1 year
Filled Product - Filled – Secondary Package	1.000.000	2 years
Intermediate Product - Bulk	3.000.000	6 years
Bacteria strains master and work banks	5.000.000	8 years

* The values of quantity supplied and / or time of contract can be changed according to contractual negotiation

2.5 Interested parties should provide the updated health professional insert package text for the product in Portuguese and / or English.

2.6 The product object in this project must have at least 24 (twenty-four) months of shelf-life, validated by stability studies acceptable by regulatory agencies mentioned in this document.

2.7 Those interested must have a price base compatible with those practiced in the international public markets and with the referenced entities, such as PAHO (Panamerican Health Organization), UNICEF (United Nations Children's Fund). The price base for supply to the public market will be negotiated and discussed with representatives of the Instituto Butantan.

2.8 Interested parties should send the price proposal per dose, product presentation and volume range, considering the supply in a period of 12 (twelve) months, the CIF (Cost, Insurance and Freight) and the packaging of the Instituto Butantan to the public market , to know:
Range 1: <500.000 doses
Range 2:> 500.000 doses and <1 million doses
Range 3:> 1 million doses

2.9 The proposal must also mention the minimum quantity for annual supply per presentation.

2.10 Those interested in the project must include in the proposal, presentation of future territories, for joint marketing and / or supplementing supplies of the vaccine by the Instituto Butantan.

3. **DATE, TIME AND VENUE**

3.1 The Public Notice Call will be made available on the Fundação Butantan website (http://www.fundacaobutantan.org.br), for subsequent consultation by interested parties, on 18th January 2021.

3.2 If there is a need to send email by interested parties for any questions, it should be sent to novosnegocios@butantan.gov.br .

3.3 After published, a period of fifteen working days will be opened for the submission of proposals by interested companies, with an indication of the minimum bases of the interest, observing what is contained in items 2.1 to 2.10 of this Public Notice Call. The proposals should be sent to the electronic address novosnegocios@butantan.gov.br, with the indication IB – VACINA PNEUMOCÓCICA POLISSACARÍDICA POLIVALENTE (23 VALENTE).

3.4 Within twenty working days after the last day for the receipt of proposals, Fundação Butantan will publish the list of companies that submitted proposals and the proposal that best meets the interests of the Instituto Butantan, being open to any of the proposers in view of the physical records, if desired, upon written request.

4. INSTERESTED PARTIES PARTICIPATION

4.1 Participation in the public call is free for all interested parties, the official languages being Portuguese and English.

4.2 The participation in the Public Notice Call is non-binding and therefore does not require the submission and approval of the proposal.

4.3 Resolutions, opinions, suggestions, criticisms or information issued in the Public Notice Call will have an advisory and non-binding character, intended to subsidize the Instituto Butantan in the search for alternatives for the development and supply of Pneumococcal Polysaccharide Vaccine.

4.4 Fundação Butantan it will guide the choice of the partner due to the identification of the proposal that offers greater advantage to the interests of the Instituto Butantan, considering the criteria contained in item 2.1 to 2.10.

4.5 Fundação Butantan will publish on the website (http://www.fundacaobutantan.org.br), after the choice, the reasons that served as a basis for choosing a given partner.

São Paulo, 13th January 2021.