HLL BIOTECH LIMITED

(Subsidiary of HLL Lifecare Limited)
Government of India Enterprise

Modules no. 013-015, TICEL Biopark Campus,
CSIR Road, Taramani, Chennai - 600113
Ph: 044-22544950
ceo@hllbiotech.com,ramanr@hllbiotech.com

GLOBAL NOTICE INVITING EXPRESSION OF INTERESTFOR STRATEGIC ALLIANCE / TIE-UP IN THE AREA OFSUPPLY OF BULK VACCINE ANDTECHNOLOGY TRANSFER OF VACCINES FOR HUMAN USE

Introduction

HLL Biotech Limited (HBL), a 100% subsidiary of HLL Lifecare Limited, a Government of India enterprise is interested in potential partnering opportunities in the field of supply and technology transfer for production of vaccines for national immunization program:

HLL Biotech Ltd (HBL) is in the process of setting up a state of the art vaccines manufacturing facility "**I**ntegrated **V**accines **C**omplex" (IVC) for human use at Chengalpattu, near Chennai. The vaccine complex shall be the nodal centre for research, manufacture and supply of vaccines at affordable prices for the **U**niversal **I**mmunization **P**rogramme (UIP) of the Government of Indiaand also for exports.

This isa **Project of National Importance**for strengthening the immunization program of Government of Indialeading to vaccine security and consequently the health security of the nation.Various vaccines that would be manufactured in IVC are Pentavalent combination vaccine (DPT+ Hib +HepB), Hepatitis B vaccine, Hib-conjugate vaccine, BCG vaccine, Measles vaccine, Human Rabiesvaccine and Japanese Encephalitis vaccine. The annual installed capacity of IVC is estimated to be 585 million doses. Vaccines produced in the IVC shall be utilized for immunization of pregnant women, men, infants and small children against various diseases throughout the countryand if

required for export to other nations. The scope of the IVC would be expanded in future to manufacture vaccines for Meningococcal meningitis, Rota viral diarrhoea, Dengue fever Measles-Rubella and Pneumococcal pneumonia.

Invitation of Expression of Interest:

In view of the above, HBL invites **E**xpression **O**f **I**nterest (EOI) from potential partners having expertise in fields of supply, manufacturingand technology transfer of human vaccines for technology/research tie-ups for development and manufacturing of vaccines for the Integrated Vaccines Complex.

SECTION I

1. SUPPLY OF BULK VACCINES

a. Bulk antigen for Diphtheria Toxoid
b. Bulk antigen for whole cell Pertussis
c. Bulk antigen for Tetanus Toxoid (for conjugation & formulation)
d. Ready to fill bulk – Inactivated and Live attenuated JE vaccine
e. Concentrated final bulk –Hib TT conjugate
f. Ready to fill Bulk – Measles vaccine, Rubella vaccine and Measles Rubella combination vaccine.

For the supply of bulk vaccine; the bidder must be:

- Existing vaccine manufacturer, who is manufacturing and supplying D, P and T group of vaccines, Japanese encephalitis (inactivated or live attenuated vaccine) and Hib-TT bulk vaccine, Measles vaccine, Rubella vaccine and Measles-Rubella combination vaccine for human use. If manufacturer, the bidder must be undisputed owner / authorized licensee of the technology used for manufacturer.
- Existing vaccine supplier, who is supplyingD, P and T group of vaccines, JE (inactivated or live attenuated vaccine) and Hib- TT conjugate, Measles vaccine, Rubella vaccine and Measles -Rubella combination vaccinefor human use.
- The vaccine should have been commercialised for one year by 30th May, 2014.
- The vaccine should meet IP, BP, EP, USP,WHO requirements.
- The bidder must list the minimum and maximum quantities that may be offered.

- The vaccine shall be manufactured as per the requirement of WHO and National Regulatory Bodies.
- The WHO prequalified vaccine will be preferred.

2. TECHNOLOGY TRANSFERATCOMMERCIALSCALEFOR:

2.1 Haemophilus influenzae type B conjugate vaccine.

2.2 Tissue Culture based Inactivated Japanese encephalitis vaccine

- Measles bulk, Rubella bulk and formulation technology for Measles Rubella combination vaccine.

2.1 Haemophilus influenzae type B conjugate vaccine.

The technology supplier must be able to offer the following:

- Supply of characterized Master Seed Culture for polysaccharide and carrier protein manufacturing
- Polysaccharide manufacturing technology
- Carrier protein manufacturing technology
- Protein Polysaccharide conjugation technology
- Formulation technology know-how
- Standardized and Qualified /Validated Analytical testing methods pertaining to above
- Timelines for the technology transfer
- Provide training to HBL personnel at mutually agreed terms and conditions

2.2 Tissue Culture based Inactivated Japanese Encephalitis vaccine

The technology supplier must be able to offer the following:

- Technology transfer (know-how) and training for development and production of JE vaccine(cell culture based and inactivated)
- Details on the seed virus and characterization documents
- Detailed list of manufacturers / licensees – using the same technology and volume of vaccines manufactured by them.
- Supply for Pre master and Master (GMP) seed strains and cell lines
- Trial batch production and training at technology providers facility

- Supply of pre-clinical and clinical trial study reports
- Technical support during the development and production
- Support for establishment of analytical methods of formulated vaccine
- Support during pre-clinical and clinical trial studies
- Provide training to HBL personnel at mutually agreed terms and conditions

- Measles bulk, Rubella bulk and formulation technology for Measles Rubella combination vaccine.
- The technology supplier must be able to offer the following:
- Technology transfer (know-how) and training for development and production of Measles vaccine, Rubella vaccine, Measles-Rubella formulation and lyophilization
- Details on the seed virus , cell line and characterization documents
- Detailed list of manufacturers / licensees – using the same technology and volume of vaccines manufactured by them.
- Supply for Pre master and Master (GMP) seed strains and cell lines
- Trial batch production and training at technology providers facility
- Supply of pre-clinical and clinical trial study reports
- Technical support during the development and production of bulk, formulation and lyophilization
- Support for establishment of analytical methods
- Support during pre-clinical and clinical trial studies
- Provide training to HBL personnel at mutually agreed terms and conditions

For Offering the Technology Transfer; the bidder must be:

- Existing vaccine manufacturer, who is manufacturing and supplying HIB conjugate vaccine and/or Tissue Culture based Inactivated Japanese Encephalitis vaccine, Measles –Rubella vaccine for human use.
- Research and development organization that has developed the technology for Hib conjugate vaccine ,TissueCulture based Inactivated Japanese Encephalitis vaccine, Measles vaccine, Rubella vaccine and Measles- Rubella combination vaccinefor human use and have transferred the technology to vaccine manufacturing organizations for commercial production.

- The vaccine should have been commercial license for one year by 30th May, 2014.
- Undisputed owner of the technology offered for transfer /license
- The bidder must furnish the details of Organization(s) to which the technology has been transferredand volume of vaccines manufactured by them
- The vaccine shall be manufactured as per the WHO requirement and approved by the National Regulatory Authorities of the respective country, which shall be acceptable to Indian NRA.
- The WHO prequalified vaccine will be preferred.
- The vaccine should meet IP, BP, EP ,USP,WHO requirements **.**

  In addition to the above mentioned vaccines, any other vaccine of mutual interest for the bulk supply or the technology transfer may also bementioned by the parties along with the EOI.

Section II

General Information

1. **The deadline for submission of the EOI bid is 15:30Hrs (IST) on 8th July2014.** Expression of Interest shall be submitted in a sealed envelope clearly super scribing on top of envelope "EXPRESSION OF INTEREST (EOI) FOR STRATEGIC ALLIANCE/ TIE UP WITH HLL BIOTECH LIMITED IN THE AREA OF BULK SUPPLY / TECHNOLOGY TRANSFER FOR MANUFACTURING THE VACCINES". Organizations are advised to carefully review and submit all relevant information with their EOI.

2. In response to this Expression of Interest, the bidder is requested to submit the following documents, which will prove their expertise and experience in the vaccine development field:

   2.1. Background about the bidder (Organization brochure) along with an overview on the products which they handle.
   2.2. The Core Competencies/Core Area of working of the Organizations.
   2.3. Brief write-up of technology offered for transfer / licensing and the type of engagement sought with HBL

2.4. Description of Patent /Patent Application and other Intellectual Property Rights concerning the technology offered by thebidder

2.5. The bidder should have experience in India, and/or other key markets in the technology transfer/ product development of vaccines.

2.6. Audited annual report of the bidder for the last three financial years (2010-11, 2011-12, 2012-13)

2.7. A list of WHO pre-qualified Vaccine products, which the bidder has supplied

3.0 Bidders should note the following:

3.1While the Expression of Interest has been prepared in good faith, HBL does not make any representation or warranty, express or implied, or accept any responsibility or liability, whatsoever, in respect of any statement or omission herein, or the accuracy, completeness or reliability of information contained herein, and shall incur no liability under any law, statue, rules or regulations as to the accuracy, reliability or completeness of this request, even if any loss or damage is caused by any act or omission on its part.

3.2. Organizations are requested to keep the information and details strictly confidential. We are looking for your support and co-operation in getting a fully responsive Expression of Interest.

3.3. HLL Biotech Limited shall not be responsible for any expense incurred by Bidder in connection with the preparation and delivery of their EOI and other expenses.

3.4. HBL reserves the right to reject any or all the Expressions of Interest without assigning any reason thereof.

3.5. HBL reserves the right to deal with the proposal in any manner without assigning any reasons for the same. The decision of HBL in this regard shall be final.

3.6.Organizations shall also submit Power Point presentations in respect of EOIs, submitted by them. HBL may invite Organizations, if required, to make Power Point presentations of their capability in the area.

3.7. EOIs submitted in electronic formats like fax, emails etc. will not be accepted.

3.8.The Expression of Interest reaching HBL after the prescribed date and time shall be considered as late and will be rejected.

3.9.The commercial proposal will be invited from the parties once HBL short lists the parties based on the party'sexpertise and experience in bulk vaccine supply/technology transfer and product development of human vaccines. After evaluation / examination of

the offers, HBL may at its sole discretion decide further course of action. In responding to this EoI all bidders shall comply with all applicable laws and regulations in India and laws of the country of their residence.

3.10.Bidder shall not undertake (or permit to undertake) at any time, any publicity activity with any section of the media in relation to this EoI / selection process without obtaining prior written consent of HBL.

Interested bidders qualifying the above conditions may send their EOI with the necessary documents to the below mentioned address on or before 8th July 2014.

The Chief Executive Officer

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