SIIPL EFFORTS

Addressing COVID-19 Challenges

Collaboration with Themis, Austria
Measles based viral vector

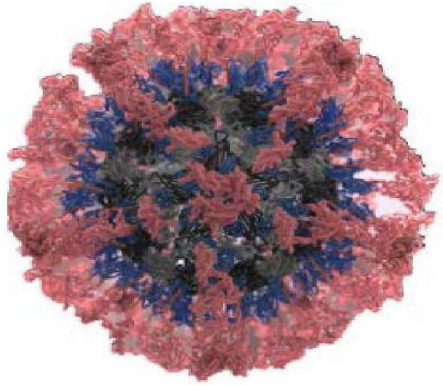
- SIIPL is collaborating with Themis, Austria and Institute of Pasteur, France for development of the vaccine against COVID-19.
- The vaccine is in early stage of development/proof of concept stage.
- SIIPL has already activated import and export of genetic material and is planning to scale up the manufacturing. As, SIIPL has full set up for Measles manufacturing and already proven supplying billions of doses, it brings a huge advantage to develop and manufacture this vaccine at SIIPL.
- SIIPL has applied to IN-CEPI for the funds.

Collaboration with Codagenix

- SIIPL has collaborated with Codagenix for the development of Vaccine which is a live attenuated vaccine against COVID-19
- At present the vaccine is in pre-clinical testing stage where in multiple clones are being tested.
- SIIPL has already activated to import the clones from the collaborator for large scale manufacturing at SIIPL.

VLP based Covid-19 vaccine in collaboration with MIT and SpyBiotech, Oxford

- SIIPL has started manufacturing development on HBsAg VLP with Spycatcher expressed in Recombinant Hansenuela polymorpha for presentation of corona RBD protein.



- Recombinant Pichia cell line expressing the receptor binding domain is being shipped to SIIPL from MIT.
- SIIPL will manufacture the bulk, fill finish and provide for clinical trials.
- SpyBiotech will conduct Phase-I/II clinical trial.
- The product candidate being expressed in recombinant yeasts with high yields, it can be manufactured in volumes excess of 200 million doses in a short time.
- The vaccine being VLP based, there is no need for novel adjuvants and can easily be formulated in proven alum based adjuvants.

Collaboration with Oxford University

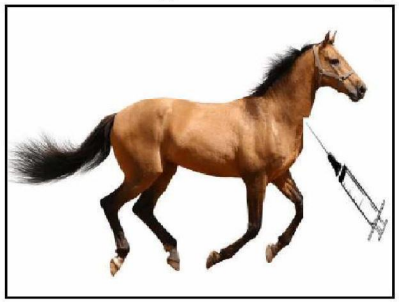
Chimp-adeno based viral vector vaccine

- SIIPL is collaborating with Oxford University for manufacturing of Chimp-adeno based viral vector vaccine (ChAdOx1) for COVID-19
- Oxford has started the clinical trial on 23rd April and by end of May, 2020 around 1100 subjects are expected to be vaccinated.
- In the meanwhile, SIIPL will stockpile the vaccine so that it is available for mass vaccination as soon as the clinical efficacy data is available. (hopefully by September, 2020)
- As on date ~ 300 volunteers might have been vaccinated.
- SIIPL would start the manufacturing optimization work as soon as it receives the biological material from Oxford (hopefully this week)

Additional efforts- Classical pathway

Equine Anti sera (Therapeutic antibodies) against Covid-19

- Highly pure equine F(ab) from the animal sera will be generated by closed loop chromatography techniques at SIIPL.
- Equines will be immunized with human interleukin 6 to generate sera and further purified to generate Anti IL-6 F(ab)s which will help to address cytokine storm in COVID-19 in late stage of the disease.



Immunization with Human IL-6

- There will be less IP related challenges as this development will be classical pathway unlike biosimilar mAb manufacturing which is highly protected by IP.
- Equines will also be immunized with spike protein and receptor binding proteins of COVID-19 virus and high titer sera will be purified to make F(ab)s which can be used for treatment of COVID positive people in early stage.
- The development can be done on fast track and indigenously at SIIPL.
- This product can be administered in combination with Stelara (Biosimilar Ustekinumab) to treat COVID-19 patients.

VPM1002 (Recombinant BCG)

- DCG(I) has given approval to SIIPL to start Phase-III clinical trial titled "A Multicenter, Phase-III, Double Blind, Randomized, Placebo controlled study to evaluate the efficacy of Recombinant BCG VPM1002 in reducing infection, incidence and disease severity of SARS-COV-2/COVID-19 among high risk subjects".
- This was culmination of sincere and well coordinated support from PMO, DCG(I) and DBT which resulted in providing the approval to start the study at a short notice.
- The recruitment is already started and the study will be carried out at ~40 sites. The protocol is based on adaptive design with use of a unique mobile app where in if the primary end point is achieved with small number of subjects, then SIIPL can approach DCG(I) for early licensure of the vaccine hopefully by July, 2020.
- SIIPL has also obtained approval to start the similar study from PEI, Germany.
- SIIPL has submitted the CTA in Australia for the similar studies and also the submissions in Canada and US are under final stages.

Capacities – Fill Finish at SIIPL

- Hugh capacities of fill finish of a good candidate (after successful clinical development) will be required for mass vaccination across the globe.
- [redacted]
- As these lines will also be used for manufacturing of other vaccines, SIIPL would require firm commitment for the required doses from Government of India.

THANK YOU