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â€œCreating affordable vaccines remains our top focusâ€?

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Q: What is the progress on Hilleman's rotavirus vaccine candidate? When do we get to see it in the market?

Our vaccine is an established one, licensed in 110 countries with 120 million doses. There is already lot of safety and efficacy data available. What we have decided is that the optimization is essential. Since it is not a new vaccine like others and has an established data system, we can go ahead with optimization and once that is over, we will go ahead with human immunogenicity tests.

The problem is that when the vaccine was originally launched, the Indian conditions were not kept in mind then. It was in liquid form which is not suitable to Indian conditions. Once you bring it out, it has to be put into expensive packaging and cold chain. In our case, if we had a vaccine that would have never been tested, we may had to take it though phase I, II, III trials which could have taken 10-11 years. But since we have data availability and vaccine being used on other populations, we are hopeful of achieving success in Indian conditions. We are hopeful of success within 2-3 years, by 2017.

Q: How do you look at vaccines being worked upon by Shantha Biotech, Serum Institute and Merdoch Research Centre?

Those are new candidates. Shantha is doing phase III studies to see whether the vaccine will be effective. This is actually what DBT and Bharat Biotech did last year. Shantha and Murdoch are even behind. However, until the third phase results are over, whether children responded to vaccine or not, we don't know. Also, whether vaccine is designed for developing nations, is not clear. All these questions are being addressed. There are different approaches but it remains to be seen which the best approach is.

Serum's vaccine has four different components that are required to be mixed prior to usage. Ours is an established vaccine.

We will not go through the phase III trials. That is why 2017 is our deadline. We will adhere to regulations and are looking forward to registration by 2-3 years. On the other hand, Serum will take 5-6 years for that, possibly by 2018-19.

Q: Given the promising nature of vaccine, have you got partners or government support for the programme?

We are in touch with various agencies and regulators. That is the reason we put our vaccine efforts in the right context. The whole process of distributing vaccine through various channels takes 6-9 months. We are trying to cut down on that by developing a vaccine that doesn't require such conditions. We have a vaccine that remains for 11 months. The bypassing of cold chain certainly will help us a lot to cut down on cold storage. Since regulators want us to get back with the set of data on the vaccine particularly there is nothing wrong with the our formulation. When we head to rural areas to ensure 100 percent immunization programme, we need to have a rough and tough vaccine. Data we have showed that the vaccine can be kept at 45 degree and thus has an edge.

Q: What are these logistic issues? How do you plan to overcome these?

The logistic issues such as handling, backup, number of health workers, increase cost. Producing cheap vaccines is not enough. We need infrastructure to make these research efforts to reach needy. But the roads, transportation are an issue. These vaccines will help a lot to solve the issue. We are trying to apply the principles to Rotavirus and that has got live virus particles compared to MenAfrivac when there were dead virus components. Chemically and structurally different. We had to bring in technology to stabilize our vaccines as compared to earlier as the concept is same but the technology. Optimize the vaccine, stabilize it. Make it easy. Our design is easy to use.

Q: Why can't all the vaccine be made on the same principle?

Our dream is that one day we will have these attributes in every vaccine. Unfortunately, when the vaccine makes start a project they think a lot about the ways to make the vaccine cheaper. And their minds are on production costs. The strategy in future will have to be on stable, cheap, logistic free vaccine.

Q: What are the current activities at Hilleman Labs?

We are a very young start up organization. Our primary activity has been to choose a focus area and strategic area. It is difficult for us to demonstrate the success. We had to focus on Diarrhoea as an area. The biggest cause of death among children of one year age in India is ether due to gastro-intestinal problems or long infections. So we carefully chose this area. We have focussed on gastro-intestinal diseases such as Rotavirus and Cholera. We plan to expand into conjugate vaccine. Other important project for us is to take this from concept to demonstrative stage. We being the not for profit organization will have to rope in partners for trials, may be in India or outside. So, we are in discussions now. We want to demonstrate the clinical success of the programme. From that stage, we will get into complex program. We will choose Dengue vaccine program whether TB, or any other area, we will look into that.

We have renewed our relationship with the Jamia Hamdard recently and shall be based out of its campus till 2018. We have involved Jamia students for our training programme and encourage them to do hands on training in a 6 monthly cycle. We also have helped university in vaccinology course. We have a workforce of 50 people, 40 permanently placed and 10 on contract.

Q: You recently signed an agreement with Gotavax on cholera vaccine? What is the progress there?

We are addressing the supply gap in this vaccine. Genetic manipulation has been done to ensure that process of production is stable. It means we started collaboration with Gotavax which is a start up at University of Gutenberg in June this year. We are working on formulation development and animal toxicology studies. We plan to complete that by the end of 2014. By next year, we plan to do the clinical testing.

So next year we will be doing clinical testing of the product. Again, We will look forward to use the accelerated platform strategy and try and seek registration. As far as the question of genetic manipulation is concerned, we will follow the standard protocols established by regulator.

Q: Is the focus now shifting towards vaccines from drugs?

I think my take is different here. With few days from HIV,TB, there are already drugs available for life style diseases. The lifestyle diseases might be prevented. But the vaccines are more required for the children. Rightly so, the government has identified the need to create healthy generation of children by vaccinating on time. Of course, drugs are going tobe important but government has recognized the importance of vaccines for the elimination of need to take drugs at a a later stage, therby

lowering the disease burden.

Q: How will your revenue be used?

R&D model has to be sustainable to accommodate the research efforts. At the moment we have core funding from Welcome Trust, UK. We hope that we will generate some revenue at the later.
When we start big clinical trials, we are hoping to manage funding from organizations such as Bill and Mellinda Gates Foundation. Other options too are being explored. Our core ability would be to license these products to manufacturers.

Q: Do you think India has enough talent available? What is your advice to the young researcher working in labs for such research?

India definitely has an advantage. We have a talent pool. Area where we are lacking is mentorship. We have to be active against the emerging diseases, we must be competent to have skills for technology handling. That's where we have a gap. That is where companies like Hilleman can chip in.

Keep an open and curious mind. Always keep in mind that the vaccine development is the fundamental contribution for society. If next generation scientists use their intellect knowledge they can surely bring about change.

Q: Where do you see Hilleman Labs ten years down the lane from now?

I see established labs and a centre of excellence for vaccine research development and partners across the world will come and partners with us for vaccine ideas from concept stage to final one. I expect that two of our products reach the development stage. We have a sustainable model that has capability to build upon innovation create effective solutions.