Cuba Produces Anti-Pneumococcal Vaccine against Seven Serotypes of the bacteria

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When she was a kid, Darielys Santana Medero dreamed of developing a vaccine. She did not believe that in order to achieve it, she just had to have the idea. She would not understand by then that a lot of effort was required to match thinking with fulfillment. But she did not remember such fantasy until now, when she noticed her child dream became reality.

And perhaps what brought those memories into her mind was the child she had inside her. She was very linked to the Project of Pneumococcal Conjugated Vaccine.

She tells the story with a smile. She answered my entire questionnaire with that same smile in one of the halls of the Center of Bimolecular Chemistry. Darielys speaks at steady pace about the course of the production of a vaccine she feels part of.

Many have contributed with efforts and years of work in the production of the vaccine. She says: “in order to make effective the production of a biologically functional product that could favorably impact our health indicators, more than one hundred people have worked hard”.

Besides, the general coordinator of the project also pointed out: “In its genesis, the research team that developed the only existing synthetic vaccine against Hib (Haemophilus influenzae) was present”.

“The group is headed by Dr. Vicente Verez as lead author. Yury Valdes, a young man who has spent all his training time as scientific, brings together and leads the human team responsible

for the creation of the Cuban vaccine conjugated against pneumococcus".

Full of sensibility, Darielys did not omit —among the main responsible of the preventive candidate— the name of Professor Violeta Fernandez Santana. "She passed away in 2011 and was closely related to the Project up to the last day of her life. On the basis of her experience in the production of a vaccine against Hib, she helped built the foundations of the path to follow in the creation of the new preparation against pneumococci. She also led and formed the group of young scientists who have developed the vaccine. In her honor, the new preparation will be registered with the name Quimi-Vio".

At present times, the vaccine is already in the final stage of its clinical trial. Now we are focusing on obtaining the registration for the age range between one and five years old. Its final target is the infant population.

"If everything goes as expected, the clinical trials will be successful. We foresee that by the end of 2016 or the early months of 2017, we could be able to carry out a massive immunization campaign to all children ranging between one and five years old. This strategy will allow us to cut the circulation of the micro-organism and impact on the disease because children under five are the most affected by pneumococcus."

"After this first step, we will continue the research so as to achieve a registration with incidence in breastfed babies. Then, the Quimi-Vio will be registered within the national immunization program".

Among Cuba's preventive vaccines, Heberpenta® was until very recently the one having more protective antigen (known as pentavalent, it has protective antigen against tetanus toxoid, diphtheria toxoid, Bordetella pertussis, Haemophilus influenza, and Hepatitis B). Nonetheless, the new candidate against pneumococcus has seven antigens of such bacteria. That being said, this is the most complex vaccine developed by the biotechnological program in the island, right behind Pfizer —made in USA, having 13 valences—, and that of Glaxo Smith Kline (GSK), from Europe, having 10.

"To define the vaccine composition, we chose the serotypes with higher incidence in the pneumococcal disease in Cuba and the Latin American region. By exploring global coverage of these serotypes in worldwide studies related to the circulation of the micro-organism, we checked that our vaccines comprise the 75% among the most frequent".

"In its design, a cost-effective approach was taken into consideration on the basis of only seven serotypes (those with higher incidence worldwide). It certainly allows a better relation complexity-effectiveness-cost in order to impact public health".

A Dangerous Species

The pneumococci are an array of bacteria belonging to the same species. The difference between them lies in the different composition of polysaccharides in the bacterial capsule. They cause meningitis (if they go to the brain), pneumonia (if they reach the lung), and generalized sepsis (if they reach the bloodstream). There are bacteria causing most of meningitis and pneumonia, especially in children; namely, the Haemophilus influenzae, the Neisseria meningitidis, and the pneumococci: Streptococcus pneumoniae.

In Cuba, the conjugated Quimi-Hib® (developed by the same group of researchers who created

the candidate in the study against pneumococci) and the VA-MENGOC-BC® provide immunization for the first two illnesses.

Having controlled this third bacterium by means of vaccination provides great impact, especially after the incidence of pneumonia and meningitis in the country. Therefore, this is a very important health issue identified in the country and a project prioritized by the MINSAP (Ministry of Public Health).

What is a conjugated vaccine?

It is a preparation in which the bacterial polysaccharide is chemically bond to the protein. Thus, we can improve the poor immune answer generated by polysaccharides in children (the bacterial capsule is a polysaccharide), thanks to a solution that protects them in the long run. It certainly allows children to be immune in their first years of life.

“Conjugated vaccines are created thanks to a technology of chemical synthesis (the composition of the preparation does not contain the bacterium). The polysaccharides are taken from the micro-organism. They are purified and some chemical modifications are made in order to bond them to the protein. Consequently, these vaccines are safer. They barely generate side effects in children.”

Why a Cuban vaccine has been developed?

The National Vaccine Program protects children from 13 infectious illnesses. However, the existing commercial vaccines are highly expensive at present times. Thus, a preparation against pneumococcus has not been included yet. This handicap will be solved with the production of a vaccine against such micro-organisms.

“There are nowadays two commercial conjugated vaccines against the bacterium in the world. One of them is Pfizer (American), and the other is known as GSK, from Europe, (Glaxo Smith Kline). Each dose is expensive in drug stores, 90 USD. And breastfed babies need at least three doses. These prices have made Prevnar 13® —from Pfizer— the most expensive drug in the history of preventive vaccines. This fact made it almost impossible for developing countries to have access to such medicines (only 30% of children worldwide have access to them). In Cuba, pneumococci are responsible for a high morbidity and caused mortality”.

“Children attending to day-care centers are at greater risk due to the actions of the micro-organism. This is a niche studied by the scientific team working with the Cuban candidate vaccine. The nasopharyngeal prevalence of the germ is found in more than 50% of children attending day-care centers in Cienfuegos. Being colonized by one of the serotypes is practically a prior condition to the disease”.

Clinical trials in children?

All registered products need clinical trials. To reach such stage, the health regulations are very rigorous. In that sense, we first must have tested it in animals (demonstrative toxicologist studies are required so as to prove there is no risk to human health) as well as the activation of the immune system by the vaccine antigen.

“The clinical stage of any candidate begins when the safety of the product is proven. Such test is carried out in a small sample of healthy volunteers. In the case of the Cuban candidate, this

requirement was tested initially in young adults. Once tested, it did not cause serious side effects and then we began to try it in children ranging from 4 to 5 years old as well as breastfed babies from 7 to 11 months. These trials, known as Stage I, showed that the preparation is safe. It allowed us to move forward to other stages involving a greater sample of children and breastfed babies.”

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