

David Foster â?? President, Isla Pharmaceuticals, Puerto Rico



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David Foster, president and co-founder of Isla Pharmaceuticals, explains the rationale behind selecting Puerto Rico as a base for the company, which aims to develop treatments for mosquito-borne disease. He highlights Isla Pharmaceuticals's unique approach of tackling diseases like Dengue fever and reveals plans for conducting follow-up clinical trials in Puerto Rico.

Mr Foster, you have been involved with multiple start-ups in the medical field prior to Isla Pharmaceuticals. What has been your strategy to ensure the success of the ventures you are involved with?

I have learned many things at my previous start-ups, which served as lessons for leading Isla Pharmaceuticals. For instance, one company was based on a great technology, but was very early stage and it ultimately did not make it. In another early stage company I founded, we recently recruited a full-time CEO, while I remain on the board. In contrast, to these companies, which were at least one year or more away from starting a phase 1 clinical trial, Isla Pharmaceuticals stands out as a rather unique and exciting story. We anticipate initiating our phase 2 clinical trials in the next few months. We are able to do this because our drug candidate has been studied by many groups for several years and has an excellent safety profile, although it has never been approved formally as a drug. Hence, there is considerable information about the compound, and clinical data that we can access, which allows us to leapfrog early stage R&D, preclinical studies and a phase 1 study.

What is the unmet medical need you strive to serve with Isla Pharmaceuticals?

We are developing a drug for the treatment of mosquito borne illnesses, which is a very important issue worldwide. Up to 700 million people are infected and more than a million die each year from mosquito borne illnesses. Dengue fever affects hundreds of thousands of people globally. In Puerto Rico it seems that almost everyone has had experience with mosquito-borne illness, either personally or within their family or group of friends. In addition, we have to be concerned with not only 4 strains of Dengue, but also Zika, Chikungunya and Yellow Fever. Zika for instance, is not only a medical problem, but also has a negative economic impact. For instance, tourist numbers dropped, because people were scared to travel to regions with Zika outbreaks. While vaccines exist for some of these diseases, they only work to a certain extent. For example, recently a Dengue vaccine received approval in the US for use in a small subset of children only. Overall, there is a huge unmet medical need and we are pursuing a small molecule, orally available drug candidate, for which we will seek approval as a preventative. At a later stage, we may also pursue a therapeutic study.

The candidate, called ISLA101, has been in phase 1 and 2 clinical studies for a variety of different indications, but has never been approved. As a result, there is considerable publicly available information about the molecule and clinical trials results. Capitalizing on this information, we are working to expedite our regulatory path. We have an incredibly exciting clinical trial lined up to study the virus on Dengue-infected subjects in a controlled hospital setting, which we expect to provide extremely clean data. Through pre-treatment with our drug we hope to see patients with reduced or no symptoms at all.

At the Puerto Rico Manufacturing Association annual convention earlier this month you highlighted that Isla Pharmaceutical's secret is to look for ways in which to tackle and do things differently. Can you give our international readers examples for this approach?

There is a huge effort to produce vaccines against these viruses. This is extremely challenging as these viruses are closely related to each other. We reasoned that rather than taking an immunological or vaccine approach, we would capitalize on the similarities of these viruses and take a small-molecule approach to target a protein used by each of these viruses, that is required for the effective lifecycle of the virus. We reasoned that if we could inhibit its activity we might have an effective product candidate. Thus far, our candidate shows activity against all four strains of Dengue as well as activity against Chikungunya, Zika and other viruses in preclinical studies.

You have spent most of your professional life in Dallas Forth Worth, Texas. Why did you decide to establish Isla as a Puerto Rican based start-up?

My business partner and co-founder, Dr William Garner, lives in Puerto Rico and became aware of the problem of mosquito-borne illnesses here on the island and in the region. After finding the right technology, we decided that the right place to establish the company in the US would be here in Puerto Rico, due to the relevance of our program and the awareness for the diseases here. In addition, there is a strong history of pharmaceutical manufacturing, biotechnology and virology expertise, as well as a medical need, which we may leverage for future follow-on studies. While our phase 2 study will take place in a controlled setting in a hospital on the US mainland, further studies may very likely take place in Puerto Rico. We may partner with academic collaborators or sponsor clinical trials on the island ourselves. Since our drug shows activity against more than only the Dengue virus, we would love to find partners for trials for Chikungunya, Yellow Fever and Zika. For these studies, we likely will not have the option of performing the studies in the controlled hospital setting like we are planning for our Dengue study, but we will likely run a conventional field study and Puerto Rico will be a great place for that.

As one of the few start-ups in the medical ecosystem in PR, what are some of the main challenges you are facing?

We have faced some administrative obstacles in setting up a company here, as the process has not always as straight-forward as we would have hoped. As a result, we hired local consultants that have helped us navigate through this environment. Another challenge has been identifying other stakeholders in the biopharma industry. Fortunately, we have developed connections at the Puerto Rico Manufacturer's Association and the Puerto Rico Science, Technology and Research Trust. These connections have proven to be extremely helpful in meeting other biopharma companies and companies supporting the industry. Finding ways to increase communication between industry

participants is an ongoing effort for me. It seems that more communication between the different stakeholders on the island would be beneficial and help to elevate the island to the next level. Nevertheless, Puerto Ricans are trying to improve the entrepreneurship environment here. For instance, the Puerto Rico Science, Technology and Research Trust is a great example of how the island is supporting start-ups, providing mentorship and funding.

What is your partnership strategy entering the next stages of product development?

During a successful round of financing last year, a large number of supporters came from Puerto Rico and have been very receptive and validated our idea of setting up the company on the island. In terms of collaborations, we are open for discussion, although we have not put our focus on finding partners yet. Our primary goal is to develop our drug candidate for Dengue fever to a more mature stage first, receiving our first clinical data in 2020. Nevertheless, for other viruses like Chikungunya, Zika and Yellow fever, we would be happy to hold a conversation with potential partners.

What are the major objectives that you want to achieve within the next 3-5 years?

We would like to see ISLA101 approved and commercialized. We are open to exploring other technologies as well, looking for opportunities in the infectious disease space to complement our portfolio. As we are currently a virtual company, we would like to establish a physical footprint in Puerto Rico in the next few years. One of our visions is to grow the company and have our product or products made in and shipped from Puerto Rico.

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