Luke Chen â?? Co-Founder and CEO, PuriBlood, Taiwan

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Luke Chen, co-founder and CEO of PuriBlood, speaks about the innovative spin-off technology developed at the

R&D Center for Membrane Technology at Chung Yuan Christian University. The companyâ??s leukocyte reduction filters have the capacity to purify blood samples twice as fast as current market standards. The samples are able to be applied in multiple areas such as plasma product development.

As CEO, please begin by introducing the origins of PuriBlood and the journey of its establishment.

Founded in January 2016, PuriBlood is a leading developer of high-end blood purification technologies and is the first technology in Taiwan to master key selective cell adsorption membranes. This technology was spun off from the R&D Center for Technology at the Chung Yuan Christian University. The company was then founded by Dr Yung Chang, director of the Membrane Center, my CTO Ken, and myself who were Dr Changâ??s PhD students. PuriBlood is the first company in Taiwan to have core technology for blood-related medical devices.

Tell us more about PuriBloodâ??s core technology and the uniqueness of the platform.

Our core technology is a zwitterionic charge-bias membrane we call ZISC. This is a charge-biased material which can capture different cell and antibodies depending on the given charge. The electrically neutral surface produced by cation and anion can effectively resist the adhesion of various molecules, including small molecules, microorganisms, plankton, and other cells. Based on zwitterionic anti-fouling, the polymer with different charges is designed to further selectively adsorb different kinds of biological cells by electrostatic adsorption characteristics. For example, the specific affinity force generated by the hydration electrostatic force field allows the white blood cells to absorb and the red blood cells pass through.

What are the potential uses that exist for this double ionic (zwitterionic) surface anti-stick(anti-fouling) treatment technology?

Human leukocyte reduction is our primary focus of use currently. However, we are working with partners to use this technology in the application of genome sequencing. This cooperation is for purifying samples to enhance the sensitivity of sequencing. This application is currently for research purposes, and we will found another company separate from PuriBlood for the future development of clinical use in genomics.

Our own PuriBlood brand is positioned primarily for customers such as hospitals and blood banks. Our products have already received FDA and TFDA approval, and we are currently working to receive CE marking.

What benefits can PuriBloodâ??s products bring to patients and how do your filters differ from the existing technology which is already on the market?

Blood transfusion can be said to be another type of organ transplant that can sustain the recipientâ??s life, but it comes with many risks. Most of the adverse reactions of blood transfusion are related to the importation of allogeneic white blood cells. Therefore, by removing these cells

before transfusion, side effects and even the transfer of viral diseases can be minimized, ultimately making the procedure safer for patients while significantly reducing the cost of medical expenses afterward.

Compared with other manufacturers, the PuriBlood filter can process the same amount of blood in a short time, the product is not affected by the temperature, and it is suitable for any non-icing area in the world. Typically, takes 15 to 20 minutes to completely filter a bag of blood, however, our filter has proven to reduce this time up to as much as half compared to existing market products. With our devices, a bag of blood only takes about seven minutes to complete with a white blood cell filtration effect as high as 99.9 percent. This will be extremely beneficial to blood banks as they can better manage their inventory rather than having to prepare large stockpiles.

The regulatory environment surrounding blood products is highly stringent, with tight laws governing the sources at the collection stage and at the storage stage to avoid contamination or infection. How does the regulatory environment surrounding blood impact the ability to innovate and diversify the offering of a company operating in this industry?

To develop this kind of product we need a large pool of blood resources which is very difficult to obtain. Therefore, we had to build a strong relationship with blood banks from the beginning. Thanks to our collaboration, the Taiwan Blood Services Foundation will begin universal leukocyte reduction in 2023. Additionally, we are in cooperation with the San Diego Blood Bank and we already have the first orders with Continental Service in Miami.

Next year, we plan to unveil our new product at the American Association of Blood Banks (AABB) Annual Meeting. This breakthrough product will allow the blood to be filtered simultaneously while being drawn from a donor. The dual-ion anti-adhesive technology is a key element in developing this kind of technology.

What production capacity does PuriBloodâ??s manufacturing facility in Zhuke have to meet market demands?

Currently, our production capacity is 1.8 million filter units per year. The products we have licensed right now are pre-start and by site, however, in the US and Europe, most blood banks are already using inline filtration systems. Although the products we have licensed are only a small portion of the market, it is enough to sustain our operations now as we prepare to scale up.

Taiwan and South East Asia will be our first market focus as we grow the company. In the future, our inline filtration system will be PuriBloodâ??s star product which will allow us to fully enter the global market. In fact, we have already entered into discussions with some huge medical device players in the market for licensing agreements.

One of the biggest challenges faced by biotechs is financing. What is your strategy to raise the funds necessary to develop, manufacture, and market PuriBloodâ??s products?

This month we completed our round A fundraising where we achieved USD 4 million which will allow us to develop our inline filter and manufacture our first products here in Taiwan. This has been a difficult challenge which we have worked for the last six months to achieve, but ultimately, we were

able to find investors not in Taiwan but in the US.

Taiwanâ??s capital market is small, and investors are very focused on a companyâ??s P/E ratio regardless of the phase it is in. This is a major challenge of course because startup companies do not have P/E ratios. Furthermore, there is a lack of education about medical device products in Taiwan whereas in markets like the US, investors make their due diligence to fully understand a companyâ??s technology and analyze its value.

What strategic objectives are you aiming to achieve as CEO of PuriBlood in the upcoming five years as the company nears a critical turning point in its development?

Before we begin focusing on international markets, we will need to be more grounded and solidify our capabilities to sell our own products here in Taiwan. Then we will expand into the US market. The second stage of our strategy will then to build our partner network by leveraging our TFDA, FDA, and CE approvals to license our products globally. Third, we will translate our filter technology into the development of plasma products as the filters also have the capability of extracting plasma samples.

What makes PuriBlood a partner of choice within the medical device industry?

One major reason is our business philosophy of wanting to improve the lives of patients. Health wellbeing and patient-centricity are at the core of PuriBloodâ??s business mission. Additionally, our innovation is our major asset. PuriBlood does not produce MeToo products, instead, the medical devices we develop are MeBetter and Me Only.

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