Frank Bedu-Addo – Co-Founder and CEO, PDS Biotechnology



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Frank Bedu-Addo shares his journey from scientist to co-founder and CEO of PDS Biotechnology. He highlights promising progress across PDS's oncology pipeline, including strategic decisions that have helped improve antitumor efficacy through combination therapy, validate science through partnerships with leading institutions, and accelerate timelines to potential regulatory approval. Bedu-Addo goes on to offers his perspective on the shifting biotech landscapes in the US and China, as well as the importance of genetic diversity in clinical trial design.

Can you tell us about yourself and the origins of PDS Biotechnology?

I earned a PhD in lipid biophysics and its applications in drug delivery from the University of Pittsburgh School of Medicine. I began my career in New Jersey at The Liposome Company. There, I focused on drug formulation development through manufacturing scale-up. Then, I moved to Schering-Plough, which merged with Merck, and I transitioned to the development of protein drugs like peginterferon alfa-2b (PEG-Intron).

My progression from bench science to the business happened when I started at Cardinal Health to head their East Coast biotech drug development operations. I built that division from scratch and oversaw all R&D and business operations, including P&L. Based on my success there, I was hired at then-startup KBI Biopharma as the fifth member of their executive team and developed and

implemented the company's operational strategy. All of these experiences positioned me well for my entrepreneurial journey with PDS Biotechnology. The scientific founder of PDS was my PhD thesis advisor and he recruited me from KBI to help found the company.

We acquired an early technology concept and went through the scientific development process to understand how it works, select the indications, and enter clinical trials. Now, our lead program is in phase III registrational trials.

Was combination therapy always the goal for PDS?

Not at first. As we went through development the industry changed and we learned more about how immunotherapy works. It became obvious that the best approach to address cancer was synergistic, where multiple technologies are used to activate different treatment pathways to help overcome tumour resistance. Our Phase I trials were still very important because it demonstrated that the monotherapy worked. This gave us the confidence to continue into phase II as combination therapy.

What makes T-cell–activating therapies unique, and how do you see them complimenting existing immuno-oncology treatments like pembrolizumab (Keytruda)?

Keytruda, a PD-1 inhibitor, and other immune checkpoint inhibitors (ICIs) have been the most successful type of immunotherapy. ICIs block immune checkpoints and reactivate a patient's T cells. The limitation is that it is dependent on those pre-existing T cells. The therapy works based on the assumption that the patient's immune system has responded to the cancer and generated relevant T cells that can be activated to attack the tumours. It is like having an army, and only select soldiers in the army know how to identify this specific enemy. However, soldiers are armed indiscriminately and there may be "friendly fire" because the T-cell soldiers may attack healthy organs in addition to the tumours. This contributes to some autoimmune side effects as ICIs unleash all T cells, not just the ones that are primed to attack the cancer.

Our PDS0101 (Versamune) technology is a subcutaneous injection that recruits T cells, trains them to recognize the cancer via unique proteins, and unleashes them to kill the cancer cells. One of the challenges of immunotherapy is getting the treatment into the lymph nodes, which are the body's T-cell generation factory. Versamune helps to do this effectively. We have seen heavy recruitment of T cells in the lymph nodes following injection. We also see a strong tumour-specific T-cell

response. For treatment to be effective, we must generate the right type, quantity, and potency of T cells.

Our lead program for PDS0101 is in head and neck cancer (HNC). The current standard of care (SOC) is Keytruda or Keytruda + chemotherapy. Median overall survival (mOS) is approximately 12-13 months, which means that if you have a recurrent metastatic HNC, you have a 50 percent chance of living 12-13 months. In our phase II clinical trial where we combine PDS0101 with Keytruda, our mOS is 39.3 months. The real impact of an effective T-cell therapy is being able to generate both killer T cells and memory T cells for a durable anticancer effect.

We believe there is a lot of potential for synergy with both immunotherapy and chemotherapy. In one study of patients with cervical cancer, researchers combined PDS0101 with the SOC, chemoradiotherapy. For the SOC, three-year survival rate for patients with locally advanced cervical cancer is approximately 75 percent. When combined with Keytruda, it jumps to around 81 percent. In the patients who received all five doses of PDS0101 + SOC, three-year survival and progression-free survival (PFS) rates were both 100 percent. In patients who received two or more doses, the three-year survival rate was around 84 percent.

Can you speak about your antibody-drug conjugate (ADC) development programme?

We are developing PDS01ADC, which is an immunocytokine. Interleukin 12 (IL-12) is fused to an antibody that binds to free DNA, which is typically found in tumour cells. IL-12 has not reached its therapeutic potential. It is a T-cell activator, but it is inflammatory and can induce fatal cytokine storms. However, we can limit the inflammation by targeting the IL-12 into the patient’s tumour instead of allowing it to circulate in the blood.

In patients with recurrent metastatic HPV-positive cancers, a study from the National Cancer Institute (NCI) showed that PDS01ADC + PDS0101 + ICI improved mOS when compared with PDS0101 + ICI. In patients for whom ICI therapy has failed, published data suggest a three- to four-month mOS, but in this study those patients saw a 17- to 19-month mOS – a significant improvement over SOC.

Our collaborations with the NCI have allowed us to evaluate other types of cancers and combinations. Recently, we announced encouraging preliminary data from our colorectal cancer (CRC) and castration-resistant prostate cancer (CRPC) studies.

Where is PDS0101 in its development, and is it on an accelerated approval path by the Food & Drug Administration (FDA)?

The combination has fast track designation from the FDA. However, when you have an overall survival primary endpoint, death events are required. We are keeping patients alive longer, but then it takes more time to reach the numbers of death events needed to achieve the endpoint.

With guidance from the FDA, we pivoted to PFS as our primary endpoint for accelerated approval while retaining the mOS endpoint for full approval. We anticipate this will speed up our development timeline and we aim to file a Biologics License Application (BLA) in the next 2 years.

As a founder and CEO, how do you see today's biotech environment, and how does it shape your strategy as you lead PDS toward commercialization?

While R&D collaborations are vital, commercial partnerships are equally important. Therefore, we needed a clear understanding of the path to commercialization. Accelerating our development timeline through FDA Fast Track Designation was a strategic decision that has significantly aided our discussions with potential partners and investors. To succeed today, biotech's must maintain a horizon view of their milestones and a definitive timeline to reach them. We see a more discerning investor attitude that requires both rigorous science and a clear execution plan.

From 2019 to 2021, there was a great deal of exuberance and capital flowing into biotech. Many companies were likely overvalued, and several IPOs involved firms that perhaps were not yet mature enough to go public. Now, the pendulum has swung completely; it is almost as if there is not enough capital to fund all the companies doing truly excellent science.

At PDS, we understood there would be skepticism, as T-cell therapies have been largely unsuccessful over the last 30 to 40 years. This led us to define collaboration as a cornerstone of our strategy. Our research partnerships with institutions like the NCI and MD Anderson Cancer Center began as early as the preclinical stage because we knew it was essential to have experts on board who could help validate our science.

Once these relationships were established, researchers recognized the clinical potential of PDS0101 through their own independent studies and proposed further clinical trials. This provided a vital opportunity for independent validation, mitigating the skepticism that often follows data from a single trial. Today, our strongest survival data comes from three independently conducted studies of PDS0101. Having this data from leading cancer institutes provides the external

validation necessary to reduce risk and build investor confidence.

How do you view the dynamic between the US and China's biotech ecosystems, and are we approaching a turning point?

When comparing China and the US, there is far more collaboration across the table than there was a decade ago. Funding or partnerships originating in China were once viewed as less valuable than those from the US or Europe, but I no longer believe that is the case. Chinese companies have made incredible strides with solid science and robust product pipelines. In fact, there is likely more available funding in China today than in the US.

From a development perspective, we are seeing an increase in clinical trials conducted in China. In the immunotherapy space, we must prioritize genetic diversity. While our asset was designed to be independent of genetic background, we conducted our Phase 2 studies in the US and Europe and are running Phase 3 studies in the same locations to mitigate risk. Because certain genetic predispositions can affect efficacy, the FDA is insistent on seeing diverse data, even for studies performed solely in the US. How we utilize data from countries like China will become increasingly important as therapies become more personalized and product approvals become more global.

Looking forward, what is your long-term vision for PDS Biotechnology?

We hope that PDS0101 can help address one of the most rapidly growing cancers in the US today, HPV16-positive HNC. This cancer is projected to surpass traditional HNCs, which are typically tobacco- and alcohol-associated, and become the most common type within the next two to five years. It is a huge unmet medical need, and we aim to get our product to these patients in the next few years. We hope that approval will allow us to rapidly expand the pipeline into other important indications like prostate cancer, breast cancer, non–small cell lung cancer, melanoma, and several other debilitating cancers. We hope that in the next two years we will see our T-cell approach enter the market and cause a resurgence in the development of this type of cancer therapy.

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