Ambovex® Immunotherapy

Introduction

Ambotan Pharma has been working on the development of AMBOVEX®, a U.S.-patented immunomodulatory medicinal botanical oral solution, containing a conjugated drug substance at a concentration of 8.0% (Patent #7744929, June 29, 2010). In 2013, Ambotan Pharma submitted an Investigational New Drug (IND) application for AMBOVEX® to the US Food and Drug Administration (FDA) under IND #115097.

Groundbreaking research on AMBOVEX® was published in the Journal of Hepatocellular Carcinoma in 2015[i], demonstrating its potential as a novel immunological modulator for the treatment of HCC in liver through a Phase II clinical trial.

Studies and Results

Ambotan Pharma has dedicated the past 18 years to the development of AMBOVEX®, conducting a series of rigorous studies to validate its efficacy and safety. We have successfully completed five significant studies:

1. Preclinical safety study in rats,
2. Preclinical toxicity and pharmacology study in mice and rats,
3. Phase-I safety clinical trial with healthy male volunteers,
4. Phase-II clinical trial utilizing AMBOVEX® via intramuscular injection (IM) in 74 patients mono-infected with HCV,
5. Phase-II clinical trial utilizing AMBOVEX® via intra-oral spray in 23 patients co-infected with HCV and Human Immunodeficiency Virus (HIV).

The compelling results from these studies have revealed AMBOVEX®'s remarkable immunomodulatory effects. Regardless of the administration method—whether intra-peritoneally, intramuscularly, or by oral spray—AMBOVEX® effectively suppresses inflammation and the progression of fibrosis. This immunotherapy treatment triggers the activation of key components of the immune system, including T-Lymphocytes CD4, CD8, macrophages, Von Kupffer, and natural killer (NK) cells.

Notably, significant changes were observed in Interferon gamma and Transforming Growth Factor beta (TGF-beta) parameters. Most importantly, there were potent immune responses induced by AMBOVEX®, leading to significant improvements in stages of necroinflammation and grades of fibrosis, as well as a remarkable reversal of cirrhosis, as indicated by liver biopsy and fibrosure data.

Building upon the extensive preclinical and clinical studies, we have identified several key advantages of AMBOVEX®:

1. AMBOVEX® serves as an immunological modulator, enabling active immunotherapy for a wide range of viral infections, including HCV/HCC.

2. It possesses the unique ability to reverse liver cirrhosis, addressing a critical unmet medical need.
3. AMBOVEX® shows promising potential for HIV treatment, as demonstrated by significantly improved T4/8 ratios and decreased serum Alfa Feto Protein levels in our Phase II clinical trial involving co-infected patients with HCV/HIV.
4. Importantly, AMBOVEX® offers a safe treatment option for cancer cells without causing any toxicity to neighboring cells or organs, such as the kidneys.

Dr. Michael Lange, Director of Research at St. Joseph's Regional Medical Center who was involved in the study commented that "Ambovex may have broad anti-fibrotic properties" and that "preliminary observations of significant reduction in the fibrosis index . . . is therefore of particular significance and needs to be investigated further."

Market Opportunity

The oncology drug market was approximately $286 billion in 2021 and expected to double by 2030. Within oncology drugs, immunotherapy drug market makes up about 25% of the market share. Given the groundbreaking results seen with Ambovex®, there is a tremendous opportunity to capture a large piece of that market share.

Next Steps

Amobtan Pharma needs to complete several more studies for FDA approval. The budget and timeline for the next stages are as follows:

	Study	Budget	Timeline
Stage 1	Nonclinical study on rats and mice. Two clinical studies	$8,000,000	6 months + 18 months
Stage 2	Phase II clinical study on 100 subjects	$15,000,000	30 months
Stage 3[1]	Phase III clinical study on 150 subjects	$30,000,000	
Stage 4[2]	Phase IV clinical study on 500 subjects	$10,000,000	

[1] Ambotan Pharma will apply for emergency review and may generate revenue to offset some costs.

[2] This is an after-market study and Ambotan Pharma will be able to generate revenue to offset costs.

Investment and Exit

Ambotan Pharma is currently seeking at least $23 million to complete Stage 1 and Stage 2 studies. The previous studies conducted by Ambotan Pharma show that positive results are expected from these studies. They are being performed again as formality for FDA approval purposes.

As Ambotan Pharma completes each stage it will see a significant rise in its valuation. The expected valuation at exit may be anywhere between $500 million and $1 billion depending on where on the timeline the exit occurs.

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4918287/