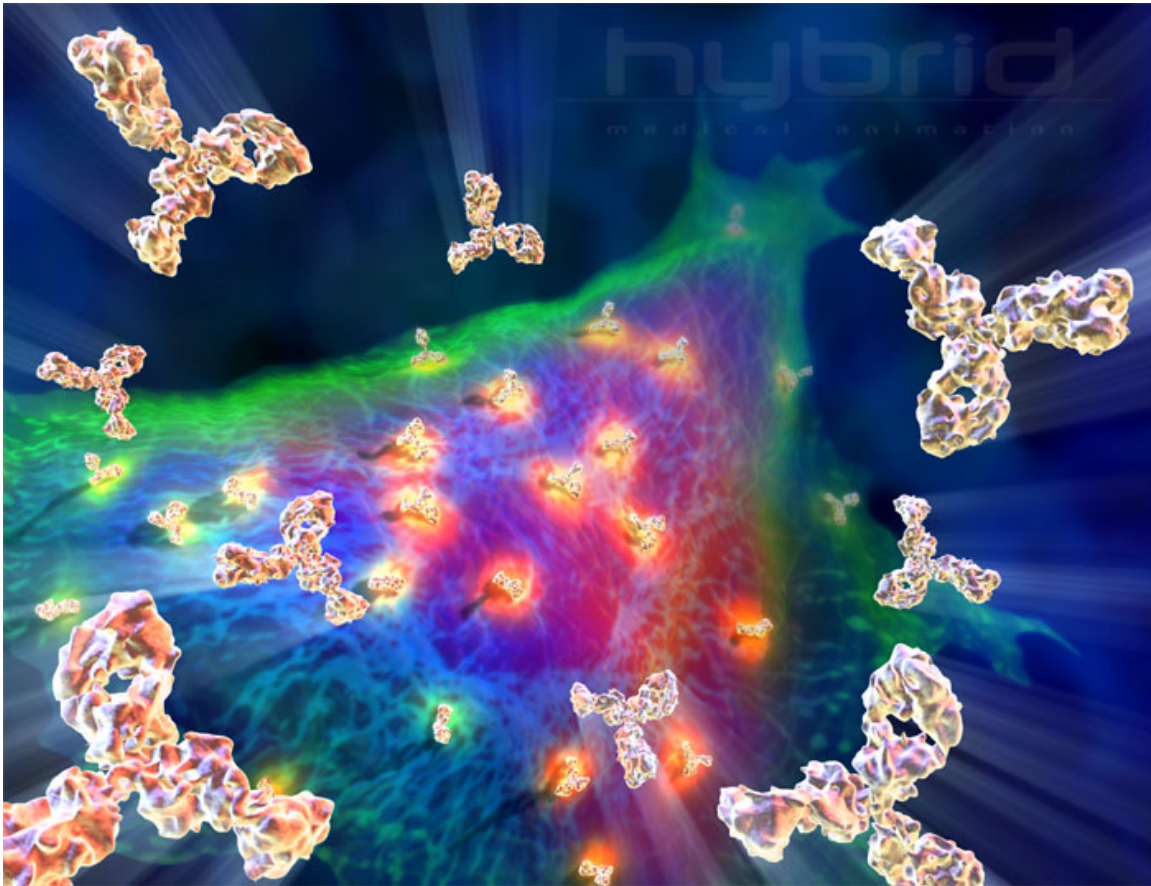

CCKK DRUG DELIVERY TECHNOLOGIES: MONOCLONAL ANTIBODIES FOR DELIVERY OF CHEMOTHERAPY DRUGS FOR CANCER THERAPY

Abstract



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1. Abstract

Malignant Gliomas affect six to nine thousand Americans every year: the average survival time for a patient with this disease is 40 to 60 weeks. CCKK Drug Delivery Technologies has developed a treatment utilizing monoclonal antibodies (MAbs) to selectively deliver a chemotherapy drug directly to the tumor cells. The MAb used, 81C6, targets tenascin, which is in the extracellular matrix of the tumor. The antibody will be attached to a micelle and the toxin will be encapsulated within the micelle. This method will increase the damage to the tumor cells while decreasing the damage to the rest of the body.

CCKK Drug Delivery Technologies will be a drug delivery technology company that will solicit other, larger drug companies to partner in the use of their drug with our immunomicelle technology. Company expenditures will be focused primarily on developing the delivery of the toxin to the cancer cell. Doing this will decrease our FDA costs because the drug manufacturer will absorb the majority of the costs.

The production facilities will be located in the Boswash, a megalopolis which runs from Boston south west to Washington DC, including Philadelphia, New York City, and Hartford, as well as all surrounding suburbs, in order to utilize the expertise and resources afforded by three of the top five cancer facilities in the U.S. as well as those of top research universities. Pre-FDA testing will be done at Johns Hopkins, Yale, or Harvard in order to employ their expertise and take advantage of available NIH funding for university research; the NIH is the major funding source for research in cancer therapy, especially at the university level. The average amount of NIH grants that can be obtained by building in this area is approximately \$3,789,000. It is estimated that the pre-FDA testing will cost between \$2.5 million and \$4.5 million and last thirteen years if the project is to advance to FDA testing. Therefore, obtaining these grants is critical to the financial feasibility of the project.

The facilities costs were estimated at \$31.5 million, including facilities for antibody, vector, and micelle production, as well as a pre-FDA research facility. The facilities for commercial production will be built during stage II of FDA testing, assuming the treatment passes all of the previous stages.

FDA trials will be conducted to determine the safety, short term side effects, and long term side effects of the treatment. FDA testing will require approximately \$20 million to fund the participating doctors' salary and patients' treatment for a duration of approximately 21.5 years.

The treatment cost per patient is set as \$15,000 per year. This price allows for recovery of the capital investment in three years with a significant profit margin. The three years begins once FDA approval is granted and production has begun. A final NPV of the most likely scenario is around \$100 million.