CEO CFO

MABCURE

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With 100% Specificity For Distinguishing Between Ovarian Cancer And Benign Tumors In Their Clinical Trials In Europe, MabCure Inc. And Its Antibody Technology, Through A Simple Blood Test Is Offering Hope For The Reduction In Miss-Diagnosis And Possible Early Detection

Healthcare
Diagnostics and therapeutics - Cancer
(MBCI.OB)

MabCure Inc.

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Dr. Amnon Gonenne
President and CEO

BIO:
Dr. Gonenne is President and CEO of MabCure. He has been a senior executive for a number of U.S. biotech companies, the CEO of Immunotherapy Inc., and CEO of Elscint Biomedical (a biotech VC fund in Israel). Dr. Gonenne was involved in the clinical development of a number of genetically engineered drugs such as human growth hormone, recombinant hepatitis B vaccine, and others. Dr. Gonenne holds a doctorate degree in Biochemistry and Biophysics from Syracuse University, New York and completed his post-doctoral training at the University of California San Diego, School of Medicine.

Company Profile:
MabCure is a biotechnology company whose mission is to change the perception of cancer as being a largely incurable disease. MabCure owns proprietary technology for the creation of unique and highly specific monoclonal antibodies (MAbs), which the company plans to develop as diagnostic tools, imaging agents and therapeutic drugs to treat lethal cancers. The company's initial focus is on the development of novel diagnostic tests for the early detection of ovarian, prostate, and colorectal cancers, each with multi-billion dollar global market potential.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Gonenne, there are some exciting things going on; what is the focus at MabCure today?
Dr. Gonenne: MabCure is a biotech company that operates in the monoclonal antibody space, which means that we are developing antibodies with a primary target being cancer. The antibodies we are developing are for three different applications. First, for diagnosis of early cancer, second for imaging the disease and third as therapeutics. Our leading candidates right now are two sets of antibodies, one against the ovarian cancer and one against prostate cancer.

CEOCFO: Why did you choose those areas to target?
Dr. Gonenne: We chose the target areas because there is a true unmet clinical need in both areas. I think the public at large knows that early diagnosis of cancer is an important thing, but I don't think that the degree of the importance is really understood by most people. For example, if ovarian cancer is discovered early then, according to the National Cancer Institute figures, the patient has a five-year survival of about 90%. If it is discovered, as it is now, in stage three or stage four disease, the survival is only around 23%. So there is a huge difference if you find it early or late. Likewise, in prostate cancer, if you find the disease in the early stages you are looking at 100% cure as opposed to only about 20% if the disease has metastasized. As a general rule, this applies to most cancers. The other point is that in both of these diseases there are no useful early diagnostic tests. Ovarian cancer has been a tremendous problem for women because ovarian cancer, although it is low in frequency, is the number one killer in gynecological cancers. The counter part of that is prostate cancer in men and there again the standard marker is PSA or Prostate Specific Antigen, which has been around for more than twenty years. It is a highly controversial marker and most urologists are quite skeptical about the PSA results, because it is an unreliable test. So this creates an opportunity for many companies including ourselves to try to develop something that is useful for both of those diseases.

CEOCFO: Would you tell us about the development of the antibodies and where you are in their application?
Dr. Gonenne: At this point we have developed several antibodies for several

diseases starting with ovarian cancer, prostate cancer, colon cancer, and melanoma. Our focus now is on the ovarian cancer and prostate cancer. We have recently announced the results of the study that we did in Europe, which is a small study, but never the less the numbers are quite significant in terms of the statistical power. We have generated more than 30,000 antibodies with ovarian cancer and screened them down to six, and those six were tested against serum samples obtained from confirmed ovarian cancer patients, patients with benign tumors and serum of healthy volunteers, men and young women. These were tested blindly and three of the six antibodies were able to distinguish all the benign tumors from ovarian cancer, which is remarkable. In professional lingo this is described as 100% specificity. We had 94% sensitivity, which means that we correctly diagnosed 16 or the 17 patients. We now know that there was a problem with that patient, and that patient should have been excluded from the study in the first place. Why is it important to have 100% specificity? Because it means that you have zero false positives, and in diseases like ovarian cancer when you have a diagnosis of the disease, many patients present with what we call 'pelvic mass' and all patients with pelvic mass undergo surgery to remove their ovaries. It turns out there are about a million women in the United States and an equal number in Europe every year that have this pelvic mass and 25% of them in fact have ovarian cancer; the others have benign tumors. To be able to distinguish between having ovarian cancer or not is important because it has been shown that the when patients having ovarian cancer are being operated on in the specialized centers, their prognosis is far better than those being operated on in the general hospital.

CEOCFO: Is this a blood test?

Dr. Gonenne: This is a simple blood test. We also have an ongoing study in Thailand and this study is testing both blood and urine samples.

CEOCFO: So this could be something that when you get your routine blood test they could check for as well?

Dr. Gonenne: Ultimately, a test to diagnose early cancer would be very useful in the setting of a women going for her annual checkup. So, for example, at the same time a pap smear is done, a blood sample or urine sample would be tested for early signs of ovarian cancer.

CEOCFO: Where are you in the process?

Dr. Gonenne: Right now, we are in the development stage and we are funding a number of clinical studies. Early next year we are plan to start a multi-center pivotal study in Europe. We plan in addition to add centers in the United States. The strategy is to first market the test in Europe and then pursue regulatory approval in the U.S. So we anticipate that if all goes well we will have a test by the end of next year. I want to be clear; we are not developing at this stage the test for early diagnosis. This will take a bit more time. Right now, we are focusing on those women who are at high-risk for ovarian cancer and these are defined as those women presenting with pelvic mass. Once the test is fully established and is launched in Europe, we plan to submit that data to the US FDA, and we hope the test will also be approved in the United States within a short time.

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- Dr. Amnon Gonenne

CEOCFO: What comes after ovarian cancer in our pipeline?

Dr. Gonenne: Behind ovarian cancer we have prostate cancer and there again we have a panel of several antibodies. We are essentially targeting the same kind of approach, looking first at patients at high risk and then looking to develop a test for early diagnosis of prostate cancer. Again in prostate cancer, high risk patients are those with a high level of PSA, but we know that not all the patients with high PSAs have cancer, many do not. So we do not want to subject them to uncomfortable biopsy procedures or surgeries without good reason. We hope to resolve that issue and be able to try to differentiate those who actually have prostate cancer from those who do not. Once we have accomplished that, we will proceed to look for distinguishing between the aggressive and the less aggressive forms of prostate cancer.

CECFO: Development is expensive; what is the financial picture like for MabCure today?

Dr. Gonenne: We are at the point of raising additional capital now, because as you were suggesting, clinical development is a costly procedure. So we are currently raising somewhere between $3 million to $5 million, to take us through the next couple of years.

CEOCFO: Why should potential investors pay attention to MabCure?

Dr. Gonenne: We need to address how we approach the problems compared to other companies. For example, with ovarian cancer, most of the competitors are using statistical approaches looking at patterns of several normal proteins that are changing in disease, versus their normal state. However, the changes are quite individual, so one has to use algorithmic approximation in order to get the proper results. These are not simple, and the recently approved test by Vermillion, for example, is not approved for screening ovarian cancer, it is approved only as means of assessing the risk of a women having cancer before surgery. It is not definitive, but rather gives the probability of a woman having cancer or not. In contrast, our test is black and white, because you are looking at markers, which are very specific to the disease. So you either have cancer or you don't. Our antibodies are targeted against unique markers for that specific cancer and that is true for

every antibody we make. It is true for the prostate cancer and it is true for the colon cancer, etc.

CEOCFO: Final thoughts, what should people reading about MabCure remember most?

Dr. Gonenne: We bring a novel simple approach to targeting unique markers on cancer cells, and these unique markers will allow us to provide the tools for early diagnosis, to be able to create proper imaging of the disease and ultimately create therapeutics against those targets, which are likely to be highly specific with little or no adverse reactions. This in my mind is a breakthrough that is not common to the industry.

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