

**With a 75% Response Rate from Patients who received Multiple Doses of their Adenoviral Vector CG0070 responding very well, Cold Genesys, Inc. is focused on Initiating a Phase II/III Pivotal Trial in patients with Non-Muscle Invasive Bladder Cancer with Carcinoma In Situ Disease**

**Healthcare  
Bladder Cancer**

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**Dr. Alex Yeng  
President**

**About Cold Genesys, Inc.:**

The company's first product is a proprietary oncolytic virus, CG0070, which is currently being developed for patients suffering from Non-Muscle Invasive Bladder Cancer (NMIBC) and who have failed the standard BCG therapy. CG0070 is an adenoviral vector designed to multiply specifically in cancer cells that have a distinct retinoblastoma gene (RB) disruptive pathway, resulting in targeted cancer cell death. A second important aspect of this virus is its capacity to express a powerful immune stimulating signal called GM-CSF. This cellular signaling molecule stimulates and attracts natural immune cells such as dendritic cells and T cells to the targeted cancer site. Cold Genesys' viral therapy promotes specific immunity against certain cancers by bringing natural immune cells together with specific cancer antigens. This dual mechanism, of oncolytic effects and GM-CSF expression, enables the immune system to search out and eradicate residual cancer cells throughout the body.

Our focus will be to initiate a Phase II/III pivotal trial in patients with Non-

Muscle Invasive Bladder Cancer with carcinoma in situ disease and who have failed BCG. These patients should also have refused cystectomy. In addition, an exploratory Phase II Protocol for patients awaiting surgical removal of the bladder due to muscle invasive disease is also actively being developed. The long-term development goal is to seek a comprehensive treatment plan for high risk NMIBC patients such as those with carcinoma in situ to delay or avoid cystectomy.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOCFO Magazine**

**CEOCFO:** Dr. Yeung, what is the vision at Cold Genesys?

**Dr. Yeung:** Cold Genesys is a pharmaceutical company that is focused on a product that produces a type of immunological response that is usually not found in other types of cancer treatments. It is actually a virus that causes the common cold virus, hence the name is Cold Genesys. The adenovirus will attack the cancer cells because it has a specific promoter more commonly activated in cancer cell because of Rb pathway deficiencies. It does not do a lot of harm to normal cells, and thus specifically targets cancer cells. During the oncolytic period, when the virus actually destroy the cancer cells, the virus will also make and release a type of cytokine, which is like a messenger that will actually solicit a lot of immune cells. Most people know of white blood cells, consisting of T and B cells, which are critical immune system components. These and other

cells will be attracted to the tumor site and recognize some of these released cancer proteins and can be identified by those kinds of cells so that the memory will last for a very long time, even though the destruction of the cancer cells by the regional action only lasts for a short period of time, but the memory from that exposure lasts a long time. CG0070 is virus therapy; a virus that will attack the cancer cells, but at the same time it is considered an immune therapy. That means it would stay for a long time in the body and when the cancer cells come back they will be recognized and attacked again.

**CEOCFO:** How does what you are doing compare to what is currently available or what is currently being worked on?

**Dr. Yeung:** Most cancer treatments today work essentially with surgery, radiation therapy and then chemotherapy. In a "so called" cancer immunotherapy, which is probably one of the newest arms of therapy against cancer, we are trying to train the body to develop certain immunities against cancer cells so that the immune system will recognize and kill these cells. It would not be something that would happen one time and allow cancer cells to come back and spread, which would make the cancer very difficult to treat. We are trying to develop what we call immunological diseases similar to, for example, rheumatoid arthritis or diabetes type I, where the body actually tries to eliminate their own cells. We are trying to train the body to eliminate "own" cells, because cancer cells are "own" cells. We want

to train the body to have the ability to do that, by identifying these cells and eradicating them. This is quite different than chemotherapy, which is more like a toxic substance that is more easily absorbed in cancer cells. However, because of toxicity associated with normal cells you really cannot kill all the cancer cells. Then, as you know, surgery and radiation therapy is only limited to what you can see or find. If the tumor is a very small or even microscopic, it is very unlikely that surgery or radiation therapy could provide much good for the patient. Immunological therapy is a very difficult process, but at the same time it is developing quite well in the last two or three years. It is quite different to the currently used treatment methods which are the inaudible chemotherapy, the surgery and the radiation.

**CEOCFO:** Where are you in the development process?

**Dr. Yeung:** Our Phase I and II clinical trials were actually completed in 2008, about 4 years ago. We saw very good results, which had thirty five patients treated with CG0070. Forty eight percent of these patients responded, some patients even with only a single treatment. A much higher percentage of patients who received multiple doses responded very well. The previous trial observed nearly a seventy five percent response rate in the multi-dose group. Many of those responses proved to last quite a long time, as nearly fifty percent of those patients are still living without disease. The upcoming clinical trial gives multiple doses, as we know that one single dose is not good enough to train the body to develop the immunological response. We are pleased with the result, which is why we are in the process of starting a new Phase II and III trial, which was approved by the FDA for a special protocol assessment (SPA) and should start sometime in the beginning of 2013.

**CEOCFO:** Has the medical community been paying attention or is this a little early?

**Dr. Yeung:** It is difficult to say because the clinical publication of the first trial will be out at the end of this year, but we did have some abstracts presented in various organizations, including the ASCO-GU conference this year. Many urologists know about the product, but certainly not the general public or people outside of the urology field. We are focusing CG0070 development for bladder cancer, so we are mainly in the urology field.

**CEOCFO:** How far will your current funding take Cold Genesys?

**Dr. Yeung:** We are working with a couple of pharmaceutical partners and we will know very soon how this process will go. In the mean time, we do have some internal funding and we do have shareholder funding that would take us to the second phase of the new trial. We are confident that

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**- Dr. Alex Yeng**

they will go ahead. However, to complete the Phase II and III trial, it will take about four to five years. It will be a long and expensive process, so in the mean time we will probably need some more funding, let us say, sometime in the later part of 2013 or 2014.

**CEOCFO:** What are the next steps? What do you see ahead for the next year or so?

**Dr. Yeung:** Clinical wise, we anticipate the first enrollment of patients to be in the spring of 2013 and we should complete at least fifty percent of the Phase II portion of this pivotal trial by the end of 2013. We should have some results in 2014. If they are encouraging, we will go to the Phase III portion of the trial, which will end somewhere around 2016. If the license and everything turn out very well, it will be around 2016 or 2017. It is estimated to be a five year total development process, which is a long

but at the same time, development of cancer drugs takes a long time to make sure the therapy is safe and efficacious for those patients. Therefore, we definitely have to do it slowly and make sure that it is done properly.

**CEOCFO:** Do you have any thoughts on when you might take on a partner or how you might be commercializing? Is it a bit too early for that?

**Dr. Yeung:** To commercialize, we have to wait until we have the FDA's decision or the license itself when we get approved by the FDA and designated to be a treatment for bladder cancer. Otherwise, we are working with a couple of pharmaceutical companies and other funding sources to ensure we are properly prepared to make CG0070 available in the clinic.

**CEOCFO:** What is the market opportunity in general in the bladder cancer area?

**Dr. Yeung:** The patient population in the United States who have had bladder cancer diagnosed is five hundred and fifty thousand. Many of them may or may not have a recurrence, as many patients do quite well without any other treatment.

Of this five hundred thousand there are approximately about four hundred thousand that are at risk, that will have recurrence and some of them will be eligible for CG0070 treatment, as many may be in the advanced stage of degrading. Degrading means the tumor is getting a little more aggressive. Those patients will be more likely to be ready to have their bladder taken out, because they are afraid it will spread and progress to other parts of the body, which could be life threatening. For those kinds of patients, we estimate anywhere between sixty thousand or so, they will probably be eligible for this therapy if it proves to be successful. However, that would have to depend on the results of these clinical trials.

**CEOCFO:** Why does Cold Genesys stand out?

**Dr. Yeung:** It is one of those “so called” cancer immunotherapy's that

has recently received a lot of attention, because it is one of the therapies that really does not have the common toxicity associated with chemotherapy. The patient will not suffer from hair loss and all the other stress that is usually closely associated with chemotherapy. At the same time, it has the potential to equip the immune system with memory to the cancer cells,

so in case the cancer comes back, there is a good possibility that this treatment will help to eliminate those cancer cells, not just locally, but in the whole body. At this stage, we are looking to partner with a pharmaceutical company capable of supporting CG0070 development through the Phase III portion of the trial. There is an opportunity for an investor to in-

vest at this moment and interested qualified investors can always explore our website at <http://coldgenesys.net/Home.html> to learn more about CG0070.

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