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Pharma and Biotech Industries Pursue Treatments for Cardiac Inflammation

### A TREATMENT FOR ATHEROSCLEROSIS AND THE CHRONIC INFLAMMATION IN THE ARTERIAL BLOOD VESSELS

A treatment for atherosclerosis and the chronic inflammation in the arterial blood vessels could be entering a critical clinical trial phase that may result in a NOVEL 0.11 noble new treatment for heart disease. Welcome to the Clinician's Roundtable on ReachMD, The Channel For Medical Professionals. I am Bruce Japsen, the healthcare reporter with the Chicago Tribune and with me today is Dr. Lawrence Cohen. Dr. Cohen is President and Chief Executive Officer of VIA Pharmaceuticals. Dr. Cohen has served as President and CEO since VIA's formation in 2004 and before that, he worked nearly 2 decades in the biotech industry holding various executive roles and quitting that as CEO of Zyomyx, a proteomics technology company, he joined in 1999 as Chief Operating Officer. Dr. Cohen received the Ph.D. in microbiology from the University of Illinois and completed his post doctoral work in molecular biology at the Dana-Farber Cancer Institute and the Department of Biological Chemistry at Harvard Medical School in Massachusetts. He joins us today from VIA's offices in St. Francisco on Battery Street.

#### BRUCE JAPSEN:

Dr. Lawrence Cohen, welcome to ReachMD XM 157, The Channel for Medical Professionals.

#### DR. LAWRENCE COHEN:

Thank you Bruce, it's a pleasure to be here today.

#### BRUCE JAPSEN:

So, therapies that are currently being developed to treat inflammation, atherosclerosis if you will, could include VIA's lead compound and if you could tell our listeners about this product and VIA and where were headed, I think they will be excited to know that there is yet another way that the biotech industry is looking to capitalize on what is still a raging problem in this country of heart disease.

#### DR. LAWRENCE COHEN:

VIA was started in the summer of 2004 to develop the next generation of medicines for treating cardiovascular disease and it was based on science that it come out of the Department of Cardiovascular Research at Stanford and specifically what it was, was a very thorough characterization of a large tissue bank of atherosclerotic arteries which allowed us to identify what the appropriate molecular targets would be if you want to reduce inflammation on the vessel wall. Armed with this information, what we did is we went around the pharmaceutical companies and we said you have been developing anti-inflammatory drugs for other indications for years, what we would like to do is to take 1 of your drugs which you did not commercialize that was known to be an anti-inflammatory in man in another condition such as asthma and see if we can take that drugs and repurpose it or refocus it now on cardiovascular disease. So the drug that we have in the clinic is an inhibitor of an enzyme known as 5-Lipoxygenase that inhibits, the production of leukotrienes which are proinflammatory mediators that would definitely work in the vessel wall. It has been in a lot of patients before and it has been known to an anti-inflammatory on asthma and we were trying to do is to demonstrate in the series of phase II clinical trials that is ineffective anti-inflammatory now on cardiovascular disease that has the ability to lessen essentially your chance of having a second heart attack.

**BRUCE JAPSEN:**

And so a lot of our listeners are more familiar with the statins, the antiplatelets, the blood pressure medications that I think you would say only reduce risk factors of coronary disease, but they don't directly treat inflammation, do they?

**DR. LAWRENCE COHEN:**

That's, that's exactly right. They may have some side effects, but they don't treat inflammation. So you think about it. We have the #1 killer in the western world which is cardiovascular disease. There is no single drug on the market that actually treats the underlying molecular mechanism of the disease. They are only reducing the risk factors.

**BRUCE JAPSEN:**

And so where exactly is VIA right now and if you could actually name your compound, I assume it is not a brand name at this stage and sort of where VIA is in the clinical trial process?

**DR. LAWRENCE COHEN:**

Absolutely, the drug we are developing is we call VIA-2291, so at this point it has only a number not yet a name. We had licensed this drug from Abbott Laboratories in Chicago in 2005 and we felt that Abbott had done enough work on in asthma that the FDA would allow us to directly go into a series of phase to clinical trials, so let's keep the first phase which is primarily safety. Let's go into series of phase 2 clinical trials and we began those after meeting with the FDA in the third quarter of 2006. We have free trials ongoing that have interlocking data intended to show that this is an effective anti-inflammatory that works on the vessel wall. Two of those trials have completed enrollment and we will be presenting the results at the American Heart Association meeting in November in New Orleans of this year and the third trial is on track to be completed sometime on the first half of 2009.

**BRUCE JAPSEN:**

And what is involved there, I mean, how many patients have been studied and for a lot of our listeners who are not familiar with the clinical trial process, give us the basically, if you have gone into phase 2 clearly its showing to be safe, what are, what are some of the data that you have already published or already, it's already been available, what has that shown?

**DR. LAWRENCE COHEN:**

So, so the drug was developed by Abbott again and I think it was probably in the early mid 90s and what they were able to show was that it reduced inflammation and asthma and their primary endpoint was FEV1 forced expiration volume 1 and they showed that basically you could have improvements in breathing taking this drug. So, known to be an anti-inflammatory demonstrated in man and a lot of that data has been published. When Abbott had it, they call it ABT761 and you can easily find on the web these publications if you just type in ABT761. So, we have taken this drug, we are studying it in 3 clinical trials, probably an aggregate of close to 300 patients in those 3 clinical trials. The first 2 trials are done this year. The sort of the core trial is being done in patients that have had a myocardial infarction, so they have had an acute coronary syndrome event and we are testing various doses of this drug on those people to determine its ability to inhibit leukotriene biosynthesis, but also to inhibit biomarkers of inflammation which give you an indication of what's going on at the vessel wall. So, it's a dose raising trial and it's also looking for safety. The second trial that we reported at the American Heart Association is done in a procedure known as carotid endarterectomy. It is probably familiar to most of your listeners, but if you have atherosclerosis in the carotid arteries that leads to the brain, 1 of the accepted therapy is actually surgical removal of the plaque. So, you cut down to the carotid artery, it actually cut the carotid artery open and you physically scrap that plaque out and sew everything back up together again. Because of that procedure, we have been able to study patients who have been on our drug and then undergo a carotid endarterectomy and what that allows us to do is actually have access to the disease tissue following treatment with our therapy and we can make standard biological and biochemical and histochemical analysis with that to see if we have actually modified the inflammatory process in the plaque. So, those are the 2 trials that are reporting out this year.

**BRUCE JAPSEN:**

Well, if you are just joining us or even if you are new to our channel, you are listening to ReachMD, The Channel For Medical Professionals. I am Bruce Japsen, your host. I am a reporter with the Chicago Tribune, and joining me today is Dr. Lawrence Cohen.

He is the Chief Executive Officer and President of VIA Pharmaceuticals which has a product that is going to be entering next year, final phase clinical trial that treats atherosclerosis which most folks are familiar with statins as a way to treat heart disease, but this is a product that is focusing on chronic inflammation in the arterial blood vessels.

And you did say that a lot of clinical trials were done by Abbott, which sort of makes the questions that hey, this drug is so good, how become a big pharmaceutical company like Abbott did not proceed, but I am thinking it probably falls in the bucket of the fact that a lot of big pharmaceutical companies have to better focus their research on the blockbusters which opens the door for you guys to take this across the goal line if you will.

**DR. LAWRENCE COHEN:**

I mean certainly that's exactly right. If you think about the strategy and this in the age of building, a small pharmaceutical company that has the ability or has an edge if you will, can compete with large pharma, which has exquisite resources. What we have to be prepared to work on perhaps take a higher risk and so while Abbott had discontinued their program on asthma in the 90s, at that time probably the role of inflammation, specifically this pathway was not well appreciated for atherosclerosis and so we have gone back now with current knowledge and we are sort of relooking at an older drug for a new indication.

**BRUCE JAPSEN:**

And if you think about it, all of sudden big pharma is back into looking at new ways to treat heart disease, so VIA could potentially be on a way if you are because a lot of pharmaceutical companies are looking at, they are looking beyond statins which are quite frankly

available in cheaper generic form and they are looking at various ways to treat heart disease and this would probably be 1 of the newer approaches, isn't it?

**DR. LAWRENCE COHEN:**

Yeah, absolutely, I mean, as you can imagine we try to stay on pharma's radar screen, if you will, so they know who we are and they know what we are doing and so we have had conversations with all of the major, not only in this country, but also international pharmaceutical companies and I would say that the vast majority if not all are very interested in the approach and many have internal programs.

**BRUCE JAPSEN:**

And could you give us the lay of the land here on what areas are being looked at in this treatment area of inflammation and also you are not the only company that is proceeding in clinical trials, but it certainly is a competitive situation.

**DR. LAWRENCE COHEN:**

There is probably a dozen companies if you and could be more, but certainly I think it's around a dozen companies that are working in this base that would include both large pharma and smaller biotechs like ourselves. A lot of people and not a lot of people, but there are number of programs like ours that are trying to inhibit the production of leukotrienes that are proinflammatory mediators so these are molecules which actually fuel to fire if you will the inflammation and keep it going and then there are number of companies that are actually looking at adhesion molecules. A class of molecules found on macrophages and another immune cells which actually bind these cells and bring them to the site of the disease. So, there are number of approaches, but broadly spoken, I think those are to that have the most activity today.

**BRUCE JAPSEN:**

But when will physicians begin to see a product like this on the market and how will they become familiar with that, I know that perhaps next year you will be doing a broader clinical trial, so some of them may even see at then.

**DR. LAWRENCE COHEN:**

Yeah, I think so, I mean, I think that there will be a series, 1 or 2, may be 3 of the phase 3, the last phase of drug testing, clinical trials involving large numbers of patients, many thousands of patients. This be conducted at centers around the world and so I think as drugs enter that phase of testing and they become much more highly visible.

**BRUCE JAPSEN:**

And what about the regulatory process, I mean, the FDA, are they prepared to address this new category of drugs, I wouldn't think that there have been any safety issues with these type of products, but what spaced of the FDA is under a little more pressure than it use to be when it starts evaluating drugs as they get in the later stages.

**DR. LAWRENCE COHEN:**

Yeah, I think the FDA has taken a very clear path towards the approval of these types of drug. As you say, safety is key, right and so that is obviously always a baseline, if you will, the drug must be safe, but on top of that, they have taken a very clear position that this drug is intended to reduce myocardial infarctions, heart attacks, stroke, major adverse cardiac events, and so that's what they want to see measure. There are no surged measures. They are not looking for the production of biomarkers or reduction in those. They really want you to enroll sufficient number of patients, so that you can demonstrate that if you are on standard of care plus your drug, you do better. You have fewer heart attacks or strokes than patients than are just on standard of care alone.

**BRUCE JAPSEN:**

Well, with that I would like to thank Dr. Lawrence Cohen who has been our guest. You will be hearing more about his company, VIA Pharmaceuticals as their lead product designed to treat atherosclerosis, which is the result of chronic inflammation and the build of a plaque in arterial blood vessel walls as this company's product enters its final round of clinical trials in the next year.

I am Bruce Japsen of the Chicago Tribune. I have been your host and you have been listening to The Clinician's Roundtable on ReachMD and I would like to thank you today for listening.