

XBiotech Issued Patent for Antibody Therapy to Treat Chronic Sterile Inflammatory Diseases

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AUSTIN, Texas, March 11, 2014 /[PRNewswire](#)/ -- XBiotech announced today that the United States Patent and Trademark Office (USPTO) granted another key patent to support the Company's growing portfolio around its lead product candidate. The new patent grants XBiotech exclusive rights to target a unique molecule associated with chronic sterile inflammation. The patent relates to antibodies and methods of using these antibodies to treat, prevent, and detect disease progression associated with a key mediator of chronic inflammation. USPTO issuance of the patent further establishes XBiotech as a pioneer in a new generation of antibody therapy to treat the crucial inflammatory process involved in progression or exacerbation of multiple chronic diseases. The Company reports that in the past year, 7 patents have been issued relating to its lead therapy and that over 100 patent applications are currently pending.

XBiotech's Vice President of Corporate Development, Dr. Stanley Kim stated, "The '489 patent further strengthens XBiotech's intellectual property portfolio which we believe dominates the chronic inflammatory space. And by continuing to innovate and re-think every step involved in bringing new therapeutics to market, we have developed and are pursuing broad patent protection for several new ground-breaking discoveries."

BACKGROUND

Chronic sterile inflammation is a crucial process involved in the pathology of chronic diseases. Sterile inflammation stimulated by cancerous tumors results in the formation of new blood supply to tumors; in the walls of the artery, sterile inflammation results in the creation of atherosclerotic plaques and occlusive arterial disease and in the white adipose tissue, sterile inflammation reduces insulin responsiveness, an underlying cause of poor glucose control in type 2 diabetics. XBiotech's True Human™ antibody technology targets a key triggering molecule that drives chronic sterile inflammatory processes. XBiotech is re-defining chronic inflammatory disease, and revolutionizing the treatment of some of the most important diseases in the modern world.

XBiotech is using a disruptive True Human antibody technology to achieve unprecedented tolerability and safety for antibody therapy. True Human antibodies, as the name applies, are literally cloned directly from a mature human immune response and are not subject to further modification to alter natural binding activity. A True Human antibody is therefore not to be confused with so-called fully human antibodies which are, *without exception*, synthetic.

Billions of unique antibodies are produced by the immune system to potentially bind and neutralize a limitless number of potential infectious agents. Thus if the human genome contained individual antibody genes that encoded only a billion different antibodies (only a fraction of the potential antibodies), there would be 20,000-times as many genes needed just for encoding antibodies as there would be for encoding the rest of the entire human genome! The size of a single cell would have to take on monstrous proportions to contain all these antibody genes. Clearly, it would be highly impractical to encode a significant antibody repertoire in the human germline.

The hallmark of vertebrate immune systems is the ability to shuffle, recombine and selectively mutate a relatively small number of genes to create a phenomenal, essentially unlimited number of antibody genes. Elucidating the mechanisms behind the ability to shuffle germline genetic sequence to produce unique antibody genes was indeed one of the major achievements of biological research in the 20th century.

It was a remarkable discovery that cells in the body contained genetic sequences that were not in the germline and were thus not heritable. But uncovering the marvelous genetic mechanism behind antibody genes opened up a new set of problems. If antibody genes were in fact not encoded in the human genome, and the products of these genes were indeed

unique, why were these unique antibody molecules not in turn recognized by the immune system as foreign substances—like any other foreign substance such as a virus or bacteria? This question led to another cornerstone advance in medicine: understanding how the body established tolerance to antibodies.

Now well understood for the past quarter century is the process tolerance achieved through selection and deletion of antibody producing cells. When a unique antibody is made from a single antibody producing cell, or B lymphocyte, the molecule is first displayed on the surface. What happens next is crucial to deciding the fate of that cell harboring the unique antibody gene. If the antibody is harmful, or autoreactive, the cell which created it undergoes further genetic rearrangement in an attempt to produce an acceptable antibody. If the antibody it produces remains harmful, the cell is stimulated to launch a suicide program and the cell is thereby deleted. On the other hand, if the antibody is not harmful, the cell is selected and is able to grow, producing identical daughter cell clones and copious amounts of antibodies as necessary. There is no more defining feature of the vertebrate immunity than this process of selection and deletion—the fundamental step that enables antibody diversity while assuring that unique antibodies are also well tolerated by the body.

To date each and every therapeutic antibody on the market—without exception—has been derived through synthetic gene sequence modification and/or from animals. The use of the term "fully human" to describe a number of marketed therapeutic antibodies has thus created some confusion. There are indeed no human antibodies currently marketed.

The antibody targeting chronic sterile inflammation in development by XBiotech was derived from a natural antibody produced within the human body. The sequence of the antibody was thus subjected to selection processes in a human to make sure it specifically binds the intended target on the one hand, but at the same time is not autoreactive. XBiotech's True Human antibody products are expected to be the best tolerated antibodies ever developed for human therapeutic purposes.

ABOUT XBIOTECH

XBiotech is leading the commercialization of biological therapies, including the discovery and development of True Human™ antibodies. The Company's lead product candidate—now in two unique Phase III registration studies—represents a novel, breakthrough treatment for advanced colorectal cancer. XBiotech has also developed manufacturing technology to reduce infrastructure needs, lessen capital requirements and shorten lead times for development of biological drugs. New manufacturing technologies are at the heart of XBiotech's approach to next generation biological therapies, including the production of highly competitive biosimilar or biobetter products.

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