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## **CLOSING IN ON A MALE BIRTH CONTROL PILL**

### *Biotech firm licenses UMMS technology that prevents sperm from swimming*

WORCESTER, Mass.— The University of Massachusetts Medical School (UMMS) and SpermaTech AS from Oslo, Norway, have completed a license agreement for a promising drug target for a male birth control pill.

The target is a protein found only in sperm cells and it regulates the sperm's ability to swim. If the protein is not activated, sperm are unable to move through the female reproductive tract to fertilize an egg. "The world is greatly in need of a better male contraceptive that is reversible, and I'm hopeful our partnering with SpermaTech will help meet this need," said George B. Witman III, PhD, the George F. Booth Chair in the Basic Sciences and professor of cell biology at UMMS, whose laboratory discovered the protein's unique structure in sperm cells. "Because this protein is found only in sperm cells, blocking its action shouldn't have any side effects, and that makes this a very exciting drug target."

Dr. Witman is an international leader in the field of cell motility who has pioneered the application of biochemical and molecular genetic approaches to the study of cilia and flagella, which are the tiny hair-like structures that are found in many parts of the human

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body. Defects in these structures can cause a variety of diseases, including chronic sinusitis and bronchitis, as well as blindness and male infertility.

Dr. Witman is the director of the Training Program in Cell and Molecular Biology of Reproduction at UMMS, and also the former director of the Male Fertility Program at the Worcester Foundation for Biomedical Research, an internationally renowned private research institute that merged with UMMS in 1997. During his tenure at the foundation, Dr. Witman worked for some 10 years with Dr. Min-Chueh Chang who, along with Dr. Gregory Pincus, developed the first female birth control pill in the 1950s. “During those years, I had many conversations with Dr. Chang about the need for a male birth control pill. So this work has been a focus of my lab for quite some time,” Dr. Witman said. “We set out to try and understand how the sperm tail generates movement. I thought there had to be a protein in the tail essential for that movement and which occurred no where else in the body. That’s what led us to this discovery.”

When sperm cells form in the testes, their tails are in place but they do not move. As sperm pass through the epididymis (a long, coiled tube that connects each testis to the vas deferens) they mature and acquire the ability to swim. Working with ram sperm, Dr. Witman, aided by his colleague Jovenal San Agustin, PhD, instructor in cell biology, found a protein within the sperm cells that is activated during the passage through the epididymis. Once activated, the protein, which he named  $C_s$ , turns on the sperm’s molecular motors, causing the tail to move back and forth, creating forward motion. Dr. Witman’s discovery of the  $C_s$  protein was first described in a 1998 paper in the *Journal of Biological Chemistry*.

One of the founders of SpermaTech, Bjorn Steen Skalhegg, PhD, a professor at the Institute for Basic Medical Sciences at the University of Oslo, has also worked for several years on sperm cell motility. Both in Oslo, and during his post-doctoral work at the University of Washington in Seattle, Dr. Skalhegg has explored the complex protein

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interactions in sperm and other cells. At the same time Dr. Witman made his discovery, Dr. Skalhegg in collaboration with professor G. Stanley McKnight at the University of Washington, Washington State, USA, developed a mouse model without the gene that expresses the C<sub>s</sub> protein. When those mice matured, tests showed that the male mice produced sperm; however those sperm were unable to move forward and fertilize the females' eggs.

In 1999 Dr. Skalhegg and several partners filed a patent application on C<sub>s</sub> and have to day an approved patent in Europe, where as the patent approval is pending in Canada, Australia and Japan. In 2001 they formed SpermaTech for the expressed purpose of developing a male birth control pill. Dr. Skalhegg's team then approached UMMS to enter negotiations to license the U.S. patent issued for Dr. Witman's technology as applied to the C<sub>s</sub> protein. The two groups met face-to-face last summer in Worcester, and the talks culminated in an agreement signed on January 17, 2005 giving SpermaTech the right to use the C<sub>s</sub> technology to develop a male birth control pill. "We are all very excited about this effort, because the contraceptive pills now available are based on hormones, which float around in the body and have significant side-effects elsewhere," Dr. Skalhegg said. "With C<sub>s</sub> only in the sperm, we believe a drug can be developed that will be an effective contraceptive, without impacting any other areas of the body."

SpermaTech is now beginning to screen small molecular compounds to identify those that can effectively block the C<sub>s</sub> protein. The company is also beginning discussions with several large pharmaceutical companies who are interested in partnering with SpermaTech to develop a male contraceptive drug, Dr. Skalhegg said. "We can't say how long it will be before a pill is available, but the methods that we are using now to screen compounds are well established and I think we are all very optimistic that we will find a compound that will work very well," Dr. Skalhegg said.

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The University of Massachusetts Medical School, one of the fastest growing academic health centers in the country, has built a reputation as a world-class research institution, consistently producing noteworthy advances in clinical and basic research. The Medical School attracts more than \$164 million in research funding annually, 80 percent of which

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