



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce & Industry, Govt., of India)

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Ampio Pharma gets patent for its lead drug Ampion from USPTO

Ampio Pharmaceuticals Inc., a biopharmaceutical company conducting clinical trials on its three lead drugs (Zertane completed two phase III studies, Ampion-completed proof of concept studies and Optina), licensing distribution of these drugs and engaged in further drug development, has received notice of allowance from the US Patent Office of an additional patent that complements and expands its anti-inflammatory patent portfolio for its lead drug Ampion.

Gary Connell, Ampio patent counsel from Sheridan Ross PC of Denver stated, "The allowed claims in this new patent protect pharmaceutical compositions that include the use of the low molecular weight fraction of commercially available (approved) human serum albumin for any use, including the injectable used in the osteoarthritis of the knee study conducted in Australia. The allowed patent claims further strengthen Ampio's patent portfolio by providing specific coverage for a pharmaceutical composition produced using the same method by which the Ampion product in clinical trials was produced."

Dr Vaughan Clift, chief regulatory officer of Ampio noted: "A meeting with the CBER (Centre for Biological Evaluation and Research) division of the FDA is scheduled to occur by the end of April 2012. The purpose of the meeting is to obtain guidance and clarity about the path and conduct of pivotal trial(s) in the US for approval of Ampion for reducing pain in osteoarthritis of the knee. We have provided the FDA a pre-IND package that includes scientific evidence as well as the results of the osteoarthritis of the knee trial results (safety, efficacy and manufacturing data) conducted in Australia, which indicated no safety concerns and statistically significant efficacy trends compared to baseline."

Michael Macaluso, CEO and chairman of Ampio, noted, "Ampio already possesses a comprehensive portfolio of issued patents and pending patent applications on Ampion, including composition of matter, methods of use and synthesis patents of the naturally occurring innate, human, anti-inflammatory small molecule diketopiperazine (Ampion). The allowance of this new patent is an important addition to our already strong intellectual property position for the Ampion product. The outcome of our scheduled meeting with the FDA will determine whether Ampio pursues this indication/trial(s) on its own or partners with a larger pharmaceutical company. Either way, we have significantly increased the economic value of our lead biological drug in a much shorter time and at a lesser cost than is customary in the pharmaceutical industry. This exemplifies our commitment to raising shareholder value while minimizing shareholders risk."

Ampion is a non-steroidal anti-inflammatory drug that appears to have a significant role in the homeostasis of inflammation, so that it has the potential to be used in a broad array of inflammatory conditions which impact millions of patients. It is a molecule produced by humans in response to

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injury and is protected globally by composition of matter and use patents including means of synthetically manufacturing the molecule and method of extraction from commercial albumin preparations.

Ampio Pharmaceuticals Inc. develops innovative proprietary drugs for inflammation, eye disease, kidney disease, CNS disease, metabolic disease and male sexual dysfunction.

Source: Pharmabiz.com

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