

**Title: Gene Therapy of Cancer using a Transmembrane IL-2 Construct**

<b>Invention Summary</b>	<p>Interleukin 2 (IL-2) is a cytokine protein necessary for production of immune cells that are involved in recognition of aberrant or malignant cells and eradication of tumors. It has been hoped that IL-2 might play a central role in cancer immunotherapy—battling cancer by revving up the immune system. Unfortunately, IL-2 can only be tolerated in small doses by the body. In dose escalation studies, patients treated with high doses of IL-2 showed clinical responses, although severe toxicity exemplified by widespread edema and other problems due to blood vessel leakiness were seen. Dr. Samlowski and colleagues have developed a method to target IL-2 specifically to tumor cells to decrease its systemic toxicity. The invention provides an approach to gene therapy using a novel fusion gene consisting of cytokines plus a transmembrane domain. The goal is to cause intratumoral expression of activating cytokines resulting in enhanced activation of cytotoxic tumor-infiltrating lymphocytes within tumors.</p>	
<b>Market Applications</b>	<p>Intervenous administration of recombinant human IL-2 is FDA approved for the treatment of cancer. IL-2 has demonstrated activity against renal cell, melanoma, lymphoma, and leukemia. The market in Interleukin 2 therapeutics is estimated to be worth more than US\$150 million per year. This would increase precipitously if the systemic toxicity were ameliorated.</p>	
<b>Features, Benefits &amp; Advantages</b>	<ul style="list-style-type: none"> <li>• The low level of cytokine expression created by the expression of the plasmid encoding the membrane-bound cytokine remains localized to the tumor and is thus not associated with the toxicity observed with high systemic doses of cytokine</li> <li>• Treatment with IL-2 has already been proven effective, so the barrier to market would be decreased.</li> </ul>	
<b>Intellectual Property &amp; Development Status</b>	<p>A formal patent application has been filed with the PCT and was subsequently nationalized to the U.S., Canada, Europe and Australia. Publication number: <b>WO 04/080404 A2</b> This technology is part of an active and ongoing research program that has been demonstrated to work in proof-of-concept experiments which includes a working prototype that has been validated in animal experiments. It is available for developmental research support and licensing under either exclusive or non-exclusive terms.</p>	
<b>Related Research</b>	<ul style="list-style-type: none"> <li>• <a href="#">Dr. Samlowski's Web Page</a></li> </ul>	
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