

**11-TTAG-016**

<b>Company Name</b>	Tocol Pharmaceuticals LLC
<b>NAICS</b>	541712
<b>Address</b>	94 Woodlore Circle
<b>City</b>	Little Rock
<b>State</b>	AR
<b>ZIP</b>	72211
<b>County</b>	Pulaski
<b>Number of Employees</b>	0
<b>Year Established</b>	2009
<b>Company Web Site</b>	
<b>Contact Person</b>	Philip J. Breen, Ph.D.
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<b>Resource Provider</b>	EnableVentures, Inc.
<b>RP Address</b>	2400 Brookhaven Dr.
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<b>RP County</b>	Crawford
<b>RP Project Contact</b>	Sharon C. Ballard

<b>RP Title</b>	President/CEO
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<b>Project Area</b>	<a href="#">None of the above - 32 - (Please provide short description in box provided below)</a>
<b>Project Area Brief Description</b>	Pharmaceuticals: production and testing
<b>Federal Agency</b>	<a href="#">U.S. Department of Health and Human Services</a>
<b>Project Title</b>	11-TTAG-016 - Development of Radioprotective Agents with Increased Bioavailability
<b>Competitive Challenges</b>	<p>Area: Research &amp; Development scientists: synthetic &amp; analytical chemistry and pharmacokinetics.</p> <p>We will be developing a radioprotectant / radiomitigator which selectively protects normal cells without protecting cancer cells. This drug will increase the therapeutic ratio of radiation treatment of cancer. The drug will accomplish this by raising the value of the minimum toxic radiation concentration (that is, the level of radiation that produces toxicity in normal cells). The ability of safely employing higher levels of therapeutic radiation should increase the efficacy of radiotherapy. As a side benefit, this radioprotectant / radiomitigator could be used to increase survival in cases of radiological accidents or terrorism.</p>
<b>Specific Problem</b>	NIH NCI # 291
<b>Solution</b>	<p>Gamma and delta tocotrienol have shown promise as good radioprotectants / radiomitigators; however, these compounds have poor oral bioavailability. We have conducted <i>in silico</i> studies which identify a chemically related compound likely to have improved transit out of the liver and into systemic circulation after oral administration, thus increasing its oral bioavailability. At present we have a provisional patent status for this compound. A radioprotectant / radiomitigator with increased oral bioavailability would not need to be administered by subcutaneous injection, a limitation of the use of existing compounds. An oral radioprotectant / radiomitigator could be more easily self-administered and stockpiled for use in an emergency</p>

	situation.
<b>Implementation Plan</b>	<p>Steps in the process of demonstrating technical feasibility include</p> <ul style="list-style-type: none"> <li>• Determination of the process for synthesizing the compound in the highest yield and purity.</li> <li>• Determination of the sparing of cultured normal cells from damage after irradiation.</li> <li>• Determination of lack of protection of cancer cells after irradiation, as compared to the case of controls with no radiomitigator present.</li> <li>• Oral bioavailability studies in rodent (rat/mouse) to prove good oral absorption. The blood levels obtained in these studies will also allow the characterization of the pharmacokinetic disposition (distribution and elimination) of this compound in the species studied.</li> <li>• Design of selective radioprotection studies in the irradiated mouse, for implementation in Phase II.</li> </ul>
<b>Maintenance Plan</b>	<p>We intend to perform advanced pre-clinical work in a phase II study that will produce data for submission to the FDA for Investigative New Drug (IND) status. After this status is achieved and IRB permission has been granted, we plan to embark on early phase human trials, in consultation with the FDA. The ultimate objective of the human trials is obtaining a New Drug Application (NDA) from the FDA.</p> <p>At present, we will be partnering with scientists with access to a small animal irradiator at the Veterans' Administration Hospital in Little Rock. We will be collaborating with a scientist at the University of Arkansas at Fayetteville for assistance in the chemical synthesis phase. We will be working with the Technology Transfer Incubator at UAMS for advancing the application of this research. We have not yet identified any partners in the pharmaceutical industry for further development of this compound.</p>
<b>Step 1</b>	SBIR/ STTR grant preparation
<b>Step 1 Time</b>	20.00
<b>Step 1 Budget</b>	\$5,000
<b>Step 2</b>	
<b>Step 2 Time</b>	0.00
<b>Step 2 Budget</b>	\$0

<b>Step 3</b>	
<b>Step 3 Time</b>	0.00
<b>Step 3 Budget</b>	\$0
<b>Increased Sales</b>	\$0
<b>Retained Sales</b>	\$0
<b>CS Inventory</b>	\$0
<b>CS Labor</b>	\$0
<b>CS Materials</b>	\$0
<b>CS Other</b>	\$0
<b>II Plant</b>	\$0
<b>II IS</b>	\$0
<b>II Workforce</b>	\$0
<b>II Research</b>	\$200,000
<b>II Other</b>	\$0
<b>AUI</b>	\$3,750
<b>SOI</b>	\$0
<b>Job Retention</b>	0
<b>Job Creation</b>	0
<b>YN 90Days</b>	Yes
<b>YN Affiliation</b>	No
<b>YN Agreement</b>	Yes
<b>YN Total Project Price</b>	Yes
<b>Explain Total Project Price</b>	
<b>YN Cash Match Agreement</b>	Yes
<b>Copied</b>	No
<b>TTAG ID</b>	11-TTAG-016
<b>Signature Panel - RP AR Name</b>	EnableVentures, Inc.

<b>Signature Panel - RP AR Email</b>	<a href="mailto:Sharon.ballard@enableventures.com">Sharon.ballard@enableventures.com</a>
<b>Signature Panel - Enterprise AR Name</b>	Tocol Pharmaceutical LLC
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<b>Signature Panel - Enterprise AR Email</b>	<a href="mailto:breenphilipj@uams.edu">breenphilipj@uams.edu</a>
<b>Include in Batch</b>	Yes
<b>Batch Number</b>	NA
<b>Application Status</b>	Pending
<b>Organization</b>	ASTA
<b>BatchTest</b>	Processed
<b>Batch Date</b>	
<b>Set Batch Number</b>	
<b>Lvl4</b>	No
<b>Application Description</b>	8-Biotechnology, Bioengineering & Life Sciences
<b>SBIR-STTR</b>	Yes