

**PROTOCOL SUMMARY:**

<b>Study Title:</b>	Phase II Study of the Safety and Efficacy of Allovectin-7® Immunotherapy for the Treatment of Primary, Resectable Squamous Cell Carcinoma of the Oral Cavity or Oropharynx
<b>Vical Inc. Protocol No.:</b>	VCL-1005-207
<b>Tumor Type and Stage:</b>	Stage I and II (T1N0M0 or T2N0M0), primary resectable squamous cell carcinoma of the oral cavity or oropharynx
<b>Key inclusion criteria:</b>	<ul style="list-style-type: none"><li>▪ No prior treatment for SCC of the head and neck.</li><li>▪ Candidates for cure with complete surgical excision.</li><li>▪ Karnofsky Performance Status <math>\geq</math> 90.</li></ul>
<b>Study Phase:</b>	Phase II
<b>Number of patients:</b>	Nine to 25
<b>Study Design:</b>	<p>Patients will receive intratumoral injections of Allovectin-7® on day 1 and 15 followed by complete surgical excision of remaining tumor on day 22. Resected tumor will be evaluated for apoptosis, necrosis, and immune cell infiltration.</p> <p>If at least 1 of the first 9 patients demonstrate a response to treatment, accrual will continue for a total of 16 to 25 patients. If none of the first 9 patients respond, then study accrual will cease.</p>
<b>Study endpoints:</b>	<ul style="list-style-type: none"><li>▪ Tumor response prior to surgery</li><li>▪ Immune response (tumor necrosis, tumor apoptosis, and lymphocytic infiltration)</li><li>▪ Toxicity</li><li>▪ Time to disease progression</li></ul>
<b>Drug Name:</b>	Allovectin-7®: VCL-1005, Plasmid DNA Lipid (DMRIE/DOPE) Complex Expressing HLA-B7 and Beta-2 Microglobulin Genes, Intralesional
<b>IND No.:</b>	BB-IND 5411