LYC-55716 is a first-in-class, oral, small-molecule investigational agent that selectively activates ROR\(\gamma\) activity and decreased immune suppression in preclinical models (Figure 1).\(^1\) As a result of these analyses, HNSCC was selected as a potential expansion indication and additional testing was performed:

- ROR\(\gamma\) expression and the in vitro effects of a ROR\(\gamma\) agonist on peripheral blood mononuclear cells (PBMCs) were assessed from patients with HNSCC.
- Clinical program identified tumor types that meet at least 2 of 3 categories.
- Mutation burden.
- Tumors with immune infiltrates.
- Checkpoint inhibitor approvals.

Target-driven responses produce beneficial anti-tumor effects. Novel Immunotherapy: LYC-55716, a Small-molecule ROR\(\gamma\) Agonist, in Clinical Trials for Head and Neck Squamous Cell Carcinoma

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Figure 4. Expression of genes that support ROR\(\gamma\) expression across tumor types

Figure 7. Tumor-infiltrating lymphocytes across tumor types

Figure 9. PBMC expression of (A) ROR\(\gamma\) and (B) target genes IL17A and IL26

Table 1. Tumors selected for Phase 2a Expansion

<table>
<thead>
<tr>
<th>Target Type</th>
<th>Tumor Types</th>
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<tbody>
<tr>
<td></td>
<td>Non-small cell lung cancer</td>
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<tr>
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<td>Gastroesophageal cancer</td>
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<td></td>
<td>Head and neck squamous cell carcinoma</td>
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<td>Ovarian cancer</td>
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<td>Renal cell carcinoma</td>
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<td>Urothelial cell carcinoma</td>
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REFERENCES