Perilymphatic IRX-2 cytokine therapy to enhance tumor infiltrating lymphocytes and PD-L1 expression preceding curative-intent therapy in early stage breast cancer

Joanna Pucilowska  
_Earle A. Chiles Research Institute, Portland, OR; Providence Cancer Institute, Portland, OR_,  
Joanna.Pucilowska@providence.org

Venkatesh Rajamanickam  
_Earle A. Chiles Research Institute, Portland, OR; Providence Cancer Institute, Portland, OR_,  
Venkatesh.Rajamanickam@providence.org

Katherine Sanchez  
_Earle A. Chiles Research Institute, Portland, OR; Providence Cancer Institute, Portland, OR_,  
Katherine.Sanchez@providence.org

Valerie Conrad  
_Earle A. Chiles Research Institute, Portland, OR; Providence Cancer Institute, Portland, OR_,  
Valerie.Conrad@providence.org

Alison Conlin  
_Providence Cancer Center, Portland, Oregon_,  
Alison.Conlin@providence.org

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Authors
Joanna Pucilowska, Venkatesh Rajamanickam, Katherine Sanchez, Valerie Conrad, Alison Conlin, Shagheyegh Aliabadi-Wahle, Shu-Ching Chang, Gary Grunkemeier, Nikki Moxon, Staci Mellinger, Maritza Martel, James Egan, Monil Shah, and David B Page

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Tumor infiltrating lymphocyte recruitment after peri-lymphatic IRX-2 cytokine immunotherapy in resectable breast and head and neck carcinoma

Joanna Puciukowska, Venkatesh Rajamani, Catherine Sanchez, Valerie Conrad, Alison Conlin, Shaghahey Aliabadi-Wahlin, Shu-Ching Chang, Gary Grunkemeier, Nikol Moxon, Staci Mellinger, Maritza Martinez, James Egger, Monil Shah, David B. Page

Abstract #1625

Primary Endpoint: Feasibility

No treatment-related grade 3/4 toxicities

<table>
<thead>
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<th>Toxicity</th>
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<th>Grade 4</th>
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<tbody>
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<td>Diarrhea</td>
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<tr>
<td>Fatigue</td>
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Exploratory Endpoints: RNA Analysis

<table>
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<tr>
<th>Gene</th>
<th>Expression Change</th>
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<td>CD4</td>
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</tr>
<tr>
<td>CD8</td>
<td>Increased</td>
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</tbody>
</table>

Figure 4: IRX-2 Increases immune checkpoint, cytotoxic T-cells and leukocyte genes expression

Figure 5: Effects on peripheral T-cells

H&E | ESCB | HNSSC
---|---|---

Conclusions and Future Directions

- IRX-2 was well tolerated, with no treatment-related grade 3 or 4 toxicities or surgical delays.
- In breast cancer, IRX-2 enhances TIL recruitment and PD-1L expression (by mRNAs and miRNAs).
- Periperal immune changes were associated with Cy administration but not IRX-2 injections.

These preliminary findings will be further explored in a follow-up clinical trial that compare anti-PD-1 +/- IRX-2 as induction therapy preceding neoadjuvant chemotherapy in stage II-III triple negative breast cancer, with a primary endpoint of pathological complete response rate.

References