Background

The 40-gene expression profile (40-GEP) test categorizes patients with a primary SCC who have one or more clinicopathologic risk factors into three biological risk groups based on the likelihood of regional, nodal, or distant metastasis (Low= Class 1; Moderate= Class 2A; High= Class 2B).1

The 40-GEP test has been shown to improve risk assessment and provide more precise, individualized metastatic risk stratification when combined with current risk prediction methods.6,7

Clinical utility studies have demonstrated the ability of 40-GEP test results to guide risk- and patient management including changes to follow-up, surveillance imaging, SLNB, and ART following 40-GEP testing (Table 1).6,10

Table 1. Individualized risk-change in overall management plans are made post-40-GEP testing

<table>
<thead>
<tr>
<th>Clinicians</th>
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<th>Specific clinical recommendation changed with 40-GEP</th>
<th>Overall change in management plan recommended with 40-GEP</th>
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<tr>
<td>24 real-world users</td>
<td>6 real-world cases</td>
<td>P: IL-2, SNB, baseline nodal imaging, adjuvant radiation and chemotherapy, surveillance imaging</td>
<td>Integration of the 40-GEP Class and significantly improved recommended patient management plans in a risk-appropriate manner while delaying with guidelines.</td>
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<tr>
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<td>2 patient vignettes</td>
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<tr>
<td>4.3 dermatologists*</td>
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Methods

The two independent cohorts (n=420, validation n=598, performance11) were compared and then combined (n=1,018).

Overall event (i.e., metastasis) rates, Kaplan-Meier analysis for metastasis-free survival, and univariate Cox regression analysis were performed for both the individual and combined cohorts.

Clinical utility and management changes in the combined cohort were modeled based on the pre- and post-40-GEP test results of a published clinical impact study of real-world cases.8

Table 2. 40-GEP accurately and consistently stratifies metastatic risk

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References

18. Icahn School of Medicine at Mount Sinai, New York, NY

Conclusions

In two independent high-risk SCC cohorts, the 40-GEP consistently demonstrates significant metastatic risk stratification.

When cohorts are combined, the 40-GEP continues significant performance in identifying metastatic risk, as shown with patients receiving Class 2A and Class 2B results indicating a 4- and 11-fold increase in metastasis, respectively, when compared to those with Class 1 results.

The impact of the 40-GEP on management decisions modeled across this large cohort represents a substantial improvement in risk- and patient management decision-making.