

4) or in 3 categories: IS Low (IS0-1), Intermediate (IS 2), High (IS 3-4). Time to recurrence (TTR) was compared between Immunoscore categories.

**Results:** Immunoscore High, Intermediate and Low were observed in 39%, 47% and 14% of the cohort, respectively. Immunoscore was positively and significantly correlated with TTR. After 5 years, 97.1% of Immunoscore High patients were event-free (95% CI 94.3-100.0), followed by 94.9% for Immunoscore Intermediate (95% CI 91.7-98.2) and 91.0% for Immunoscore Low patients (95% CI 83.8-98.9) (unadjusted and stratified by participating center HR<sub>low vs high</sub>=4.86; 95% CI 1.35 – 17.44;  $p = 0.0155$ ). When adjusting the model with Immunoscore, age, gender, T-stage sidedness and MSI, Immunoscore remained the sole significant parameter (stratified by participating center HR<sub>low vs high</sub>=7.82; 95% CI 1.49 – 41.01;  $p = 0.015$ ), with the highest relative contribution (chi-squared proportion ( $\chi^2$ ) =62%) compared to the other parameters in the model. Similar significant results were found using the Immunoscore percentiles as a numeric continuous parameter. The robust correlation between Immunoscore classification and TTR was further corroborated by a separate analysis of the same cohort distributed into five IS categories (IS 0-4): Immunoscore classification – Events/total number of patients (%) – 5y event-free survival IS4 – 1/27 (6%) – 100% IS3 – 4/149 (33%) – 96.6% IS2 – 13/214 (47%) – 94.9% IS1 – 4/45 (10%) – 90.5% IS0 – 2/16 (4%) – 92.3%

**Conclusion:** Immunoscore® is a robust prognostic indicator of the risk of recurrence in stage I CC. This risk assessment tool reliably identifies a sub-group of patients with an increased risk of relapse for whom a more intensive surveillance program after curative resection may be recommended.

**O – 023** Significant differences in outcome between Immunoscore categories in stage I colon cancer patients

J Galon<sup>1</sup>, F Hermitte<sup>2</sup>, B Mlecnik<sup>3</sup>, F Marliot<sup>4</sup>, C Bifulco<sup>5</sup>, A Lugli<sup>6</sup>, I Nagtegaal<sup>7</sup>, A Hartmann<sup>8</sup>, M Van den Eynde<sup>9</sup>, M Roehrl<sup>10</sup>, P Ohashi<sup>11</sup>, E Zavadova<sup>12</sup>, T Torigoe<sup>13</sup>, P Patel<sup>14</sup>, Y Wang<sup>15</sup>, Y Kawakami<sup>16</sup>, F Marincola<sup>17</sup>, P Ascierto<sup>18</sup>, B Fox<sup>19</sup>, F Pagès<sup>4</sup>

<sup>1</sup>INSERM, PARIS, France, <sup>2</sup>HaliDx, Marseille, France, <sup>3</sup>INSERM, Paris, France, <sup>4</sup>AP-HP, Paris, France, <sup>5</sup>Providence Portland Medical Center, Portland, Oregon, USA, <sup>6</sup>University of Bern, Bern, Switzerland, <sup>7</sup>Radboud university medical center, Nijmegen, Netherlands, <sup>8</sup>Erlangen-Nürnberg University, Erlangen, Germany, <sup>9</sup>Clin. Univ. St-Luc Bruxelles, Brussels, Belgium, <sup>10</sup>Memorial Sloan Kettering Cancer Center, New York, New York, USA, <sup>11</sup>Princess Margaret Cancer Centre, Toronto, Ontario, Canada, <sup>12</sup>VFN Charles University, Prague, Czech Republic, <sup>13</sup>Sapporo Medical University School of Medicine, Sapporo, Japan, <sup>14</sup>The Gujarat Cancer & Research Institute, Ahmedabad, India, <sup>15</sup>Xi'an Jiaotong University, Xian, China, <sup>16</sup>Keio University, Tokyo, Japan, <sup>17</sup>AbbVie Inc., Redwood City, California, USA, <sup>18</sup>Instituto Nazionale Tumori IRCCS, Naples, Italy, <sup>19</sup>Robert W. Franz Cancer Center, Portland, Oregon, USA

**Introduction:** Immunoscore® is an in vitro diagnostic test that predicts the risk of relapse in patients with early-stage Colon Cancer (CC) by measuring the host immune response at the tumor site. It is a risk-assessment tool that provides independent and superior prognostic value than traditional risk parameters and is intended to be used as an adjunct to the TNM classification. Currently, the target population for Immunoscore is stage II & III CC patients, for whom individual risk-assessment plays a critical role to guide post-surgery decisions. In stage I, survival rates are high and adjuvant chemotherapy is not typically recommended. However, approximately 10% of stage I CC tumors will recur even after surgical resection.

**Methods:** A subgroup analysis was performed on the stage I patients (n = 451) from the Immunoscore international validation study (Pagès et al. The Lancet 2018). Patients were classified by Immunoscore based on pre-defined cutoffs, either in 5 (IS 0-