A phase 2 multicenter study to evaluate the efficacy of tilsotolimod in combination with nivolumab and ipilimumab for treatment of microsatellite-stable colorectal cancer (ILLUMINATE-206)

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Disclosures:
Background

• Nivolumab, administered as monotherapy or in combination with ipilimumab, has demonstrated benefit for several solid tumor types, including previously treated mismatch repair deficient (dMMR)/microsatellite-instability high (MSI-H) metastatic colorectal cancer (mCRC)\(^1\)

• Microsatellite-stable (MSS) CRC is highly immunosuppressive and typically unresponsive to checkpoint inhibitors or other immunotherapies\(^2\)-\(^4\)

• Tilsotolimod is an investigational Toll-like receptor 9 (TLR9) agonist with immunostimulatory activity\(^5\)

• In a phase 1 study in patients with advanced solid tumors (ILLUMINATE-101, NCT03052205), monotherapy with intratumoral tilsotolimod has demonstrated dendritic cell activation and increased numbers of tumor-infiltrating lymphocytes\(^6\)

• In a phase 1/2 study of intratumoral tilsotolimod plus ipilimumab in anti–PD-(L)1–refractory advanced melanoma, durable responses in injected and noninjected lesions were observed\(^7\)

A study of intratumoral tilsotolimod in combination with nivolumab and ipilimumab for the treatment of solid tumors

**Immunotherapy-naïve MSS-CRC cohort**

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<th>Inclusion Criteria:</th>
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<tr>
<td>Histologically confirmed advanced, metastatic, or progressive MSS or pMMR CRC</td>
<td>Prior treatment with agents directed at PD-1, PD-L1/2, or another stimulatory or co-inhibitory T cell receptor</td>
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<td>Received at least 2 prior regimens of therapy for advanced or metastatic CRC including fluoropyrimidine-, oxaliplatin-, and irinotecan-based regimens</td>
<td>BRAF V600E mutation</td>
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<td>Documentation of radiologic progression by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 during or after previous chemotherapy</td>
<td>History of immune-mediated colitis</td>
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CRC, colorectal cancer; MSS, microsatellite stable; pMMR, mismatch repair proficient.

For more information on this study, visit [https://clinicaltrials.gov/ct2/show/NCT03865082](https://clinicaltrials.gov/ct2/show/NCT03865082)
ILLUMINATE-206 Endpoints and Status

Study Endpoints

Efficacy based on overall response rate and duration of response per RECIST v1.1

Safety and tolerability

Exploratory: Paired blood or biopsy samples may be evaluated for tumor genetics, immune infiltrates, and gene expression

Current status

• 10 patients have been enrolled in an MSS-CRC safety cohort, with data expected in H2 2020

Thank you to the patients, investigators, and staff involved in this study

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