|  |  |  |  |
| --- | --- | --- | --- |
| ***Cohort 2*** | | | |
|  | **Combination ipilimumab and nivolumab -related colitis**  **(IN-COL)** | **Combination ipilimumab and nivolumab treated**  **with nil adverse events**  **(IN-NAE)** | **p value** |
| ***Number (N)*** | 9 | 11 | N/A |
| ***Age, median years (interquartile range)*** | 64 (53-67) | 62(55-70) | 0.42 |
| ***Sex (N and %Male)*** | 6(67) | 6 (55) | 0.69 |
| ***Melanoma Stage (AJCC v8; N)***  ***M1a***  ***M1b***  ***M1c***  ***M1d*** | a 1  b 3  c 3  d 2 | a 0  b 2  c 5  d 4 | 0.53 |
| ***Visceral Metastases (%)*** | 5(56) | 10 (91) | 0.07 |
| ***Serum lactate dehydrogenase (LDH) median U/L (interquartile range)*** | 227 (231-327) | 251(160-426) | 1.00 |
| ***IN-C “colitis” time-point or***  ***IN-NAE “TX” time-point***  ***Days, median (inter-quartile range)*** | 37 (19-46) | 42 (21-70) | 0.17 |
| ***Colitis grade (N)***  ***1***  ***2***  ***3***  ***4*** | 0  0  8  1 | N/A | N/A |
| ***Colitis treatment (N and%)***  ***IV Methylprednisone***  ***Infliximab***  ***Vedolizumab***  ***Colectomy*** | 7 (78)  7 (78)  0  0 | N/A | N/A |
| ***Histopathological features***  ***Diffuse active colitis***  ***Granulomas present***  ***Mild inflammation***  ***Mild non-specific acute colitis***  ***Mild to moderate acute colitis***  ***Moderate to marked acute colitis***  ***Severe acute proctocolitis***  ***Mixed acute and chronic colitis***  ***Chronic colitis*** | 1  2  1  1  1  1  1  1  1 | N/A | N/A |

**Table IIa) Clinical characteristics of Cohort 2 IN-C and IN-NAE groups.**

|  |  |
| --- | --- |
| ***Cohort 2*** | |
|  | **Ulcerative Colitis** |
| ***Number (N)*** | 6 |
| ***Age, median years (interquartile range)*** | 46 (25-53) |
| ***Sex (N and %Male)*** | 2 (33) |
| ***Duration of ulcerative colitis (years)*** | 5 (2-8) |
| ***Treatment to date (N)***  ***Mesalazine***  ***Azathioprine***  ***Methotrexate***  ***Prednisone***  ***Infliximab*** | 5  5  1  4  3 |
| ***Active disease at time of blood sample (N and %)\**** | 6 (100) |

**Table IIb) Clinical characteristics of Cohort 2 UC group;**

*\* According to clinical (6/6), endoscopic (3/6) and/or histopathological (3/6) criteria*