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MO29-4  Sequential afatinib and osimertinib in Asians with EGFRm+ NSCLC: combined analysis of two non-interventional studies
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Background: Sequential use of afatinib and osimertinib could be an effective strategy in EGFRm+ NSCLC pts with T790M-mediated resistance to 1st-line treatment. Two recent non-interventional trials, GioTag and UpSwinG, demonstrated encouraging time-to-treatment failure (TTF) and overall survival (OS) in pts receiving sequential afatinib and osimertinib, especially in Asian pts (median TTF: 28.8-37.1 months; median OS: 42.3-44.8 months). Here, in order to increase cohort size and facilitate response data, as well as the maximum tolerated doses for QD and BID poziotinib in Japanese patients, will be presented.
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MO29-5  Updated safety and efficacy of poziotinib in Japanese patients with non-small cell lung cancer: Phase 1 study
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Background: Poziotinib is a potent tyrosine kinase inhibitor (TKI) of epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (HER2) exon 20 mutations. The ZENITH20 global registrational study has demonstrated efficacy of poziotinib in previously treated patients with non-small cell lung cancer (NSCLC). Here, we present data from a phase 1 portion of the open-label study to determine the recommended dose (RD) and assess tolerability, safety, and efficacy of poziotinib in Japanese patients with NSCLC. The study is actively enrolling (NCT04420008).
Methods: In phase 1, patients with locally advanced or metastatic NSCLC will be treated with poziotinib in previously treated patients with non-small cell lung cancer (NSCLC). Here, we present data from a phase 1 portion of the open-label study to determine the recommended dose (RD) and assess tolerability, safety, and efficacy of poziotinib in Japanese patients with NSCLC. The study is actively enrolling (NCT04420008).
Results: In phase 1, 22 patients have been enrolled to date and 19 patients have been treated with poziotinib. For the 19 patients with analyzable data, the median age is 63 years (38-81 years), 74% are male, 84% have an ECOG PS of 1, and 63% received at least 3 prior lines of therapy. Based on the ongoing safety review (n = 19), poziotinib dosing has been escalated from 8 mg to 12 mg to 16 mg in the QD group and from 4 mg to 6 mg to 8 mg in the BID group. Overall, the most common related adverse events (AEs) were as expected for the class of EGFR TKI drugs. No Grade 4 or 5 treatment-related AEs have been reported. Dose limiting toxicities were reported in four patients.
Conclusions: In the first 19 treated Japanese patients with NSCLC, poziotinib has exhibited a mechanism-based and manageable safety profile. Updated safety and response data, as well as the maximum tolerated doses for QD and BID poziotinib in Japanese patients, will be presented.
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MO30-1  Factors critical for the acquisition of antibody after SARS-CoV-2 vaccination in malignant lymphoma patients
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Background: The acquisition of antibodies (Abs) of SARS-CoV-2 after vaccination among hematological diseases patients is inferior to that of healthy individuals. In this study, we conducted a prospective observation study (UMIN 000045150) to evaluate Ab titers achieved after vaccination in patients with hematological diseases, focusing on peripheral blood (PB) lymphocyte subsets and gamma globulin levels.
Result: This study included patients with hematological diseases (N = 263) and healthy volunteers (N = 41). The titer of antibodies after vaccination was significantly lower in the hematological disease (median: 23.8 vs. 105.6 U/mL, p < 0.001), and the percentage of positivity was also significantly lower (52.5% vs. 100%, p < 0.001). Furthermore, the results of matched analysis were similar (58.7% vs. 100%, p < 0.001). In risk factor analysis, the results showed that the numbers of CD19 and CD24 positive cells in the PB and IgM titer were significantly correlated with the acquired Ab titer. These trends were also seen in patients with hematological diseases overall, but were particularly pronounced in patients treated with anti-CD20 Ab therapeutics (N = 68). Using receiver operating characteristic (ROC) analyses, the cut-off values were calculated for CD19-positive cell count, CD24-positive cell count, and IgM level, respectively. With these criteria, the CD19-positive cell counts in PB showed the strongest correlation with increased anti-SARS-CoV-2 IgG titer (r = 0.844, p < 0.001), with 0% Ab gain for below the cut-off and 76.7% for above the cut-off. In addition, CD24-positive cell counts of above the cut-off and IgM level of for above the cut-off were significantly correlated and above the CD19 positive cell count, but the correlation coefficient was lower than that of CD19-positive cell count.
Discussion: Our analysis suggests that the number of CD19-positive cells in the PB may be a useful marker to predict the likelihood of Ab response to SARS-CoV-2 vaccination in hematological patients.
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MO30-3  Clinical characteristics of DLBCL patients experiencing early disease progression among lower IPI risk groups
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Background: We have previously reported early disease progression within 24 months (POD24) could be a surrogate marker for a substantially increased risk of death (2016 The Japanese Society of Hematology annual meeting). The aim of this study was to clarify clinical characteristics of DLBCL patients experiencing POD24 among lower International Prognostic Index (IPI) risk groups.
Methods: Subjects were consecutive DLBCL patients treated with R-CHOP based therapy and diagnosed as IPI low/low-intermediate (L/L-I) risk groups. For comparision, DLBCL patients in the risk group of IPI high/ high-intermediate (H/H-I) were also analyzed.
Results: A total of 187 patients were identified from the list of patients with newly diagnosed DLBCL at our institute. Of the patients, 126 patients were diagnosed as IPI L/I risk groups. With a median follow-up of 5.9 years, the 5-year overall survival (OS)