Camrelizumab monotherapy or plus apatinib for PD-L1- positive advanced pulmonary sarcomatoid carcinoma: A single-arm, open-label, multicenter, phase II study

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BACKGROUND – About the disease.

- Pulmonary sarcomatoid carcinoma (PSC) is a unique, highly invasive, biphasic type of pulmonary cancer with a poor prognosis.
- It represents 0.1–0.4% of all malignant tumors of the lung.
- It is insensitive to chemotherapy or radiotherapy and no optimal treatment has been established yet.
- Because of the high expression of PD-L1, ICIs were documented to possess encouraging efficacy in PSC patients.

BACKGROUND – About the drugs.

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Camrelizumab

- Programmed cell death 1 (PD-1) inhibitor.
- Received conditional approval in China for the treatment of relapsed or refractory classical Hodgkin lymphoma in 2019.
- Investigated –
  - B cell lymphoma,
  - oesophageal squamous cell carcinoma,
  - gastric/gastroesophageal junction cancer,
  - hepatocellular carcinoma, nasopharyngeal cancer and
  - non-squamous,
  - non-small cell lung cancer.

Apatinib

- Is a tyrosine kinase inhibitor that selectively inhibits the VEGFR2.
- Investigated.
  - Metastatic gastric carcinoma,
  - Metastatic breast cancer,
  - Adenoid cystic carcinoma, and
  - Advanced hepatocellular carcinoma.

METHODS

- Single-arm, open-label, multicenter, phase II study.
- Patients with an
    i. Age of 18-80 years old,
    ii. ECOG PS 0-2,
    iii. PD-L1 positive,
    iv. Histologically or cytologically confirmed stage IIIB-IV PSC regardless of prior therapy lines
- PD-L1 TPS 1-49% - Camrelizumab (200 mg Q3W) plus apatinib (250mg)
- PD-L1 TPS 50%. - Camrelizumab monotherapy (200 mg Q3W)

- The primary endpoint was ORR according to RECIST v1.1.

Characteristic	Camre+Apa N=3	Camre N=13
Age		
Median(IQR), years	62(55-66)	65(42-69)
<65 years	2(66.7%)	5(35.7%)
Sex		
Male	2(66.7%)	11(85.7%)
Female	1(33.3%)	2(15.4%)
ECOG PS, n		
0-1	3(100%)	12(92.9%)
2	0	1(7.1%)
History of smoking, n		
Smoker	1(33.3%)	9(71.4%)
Non-Smoker	2(66.7%)	4(28.6%)
Brain Metastases	1(33.3%)	2(15.4%)
Liver Metastases	0	3(23.1%)

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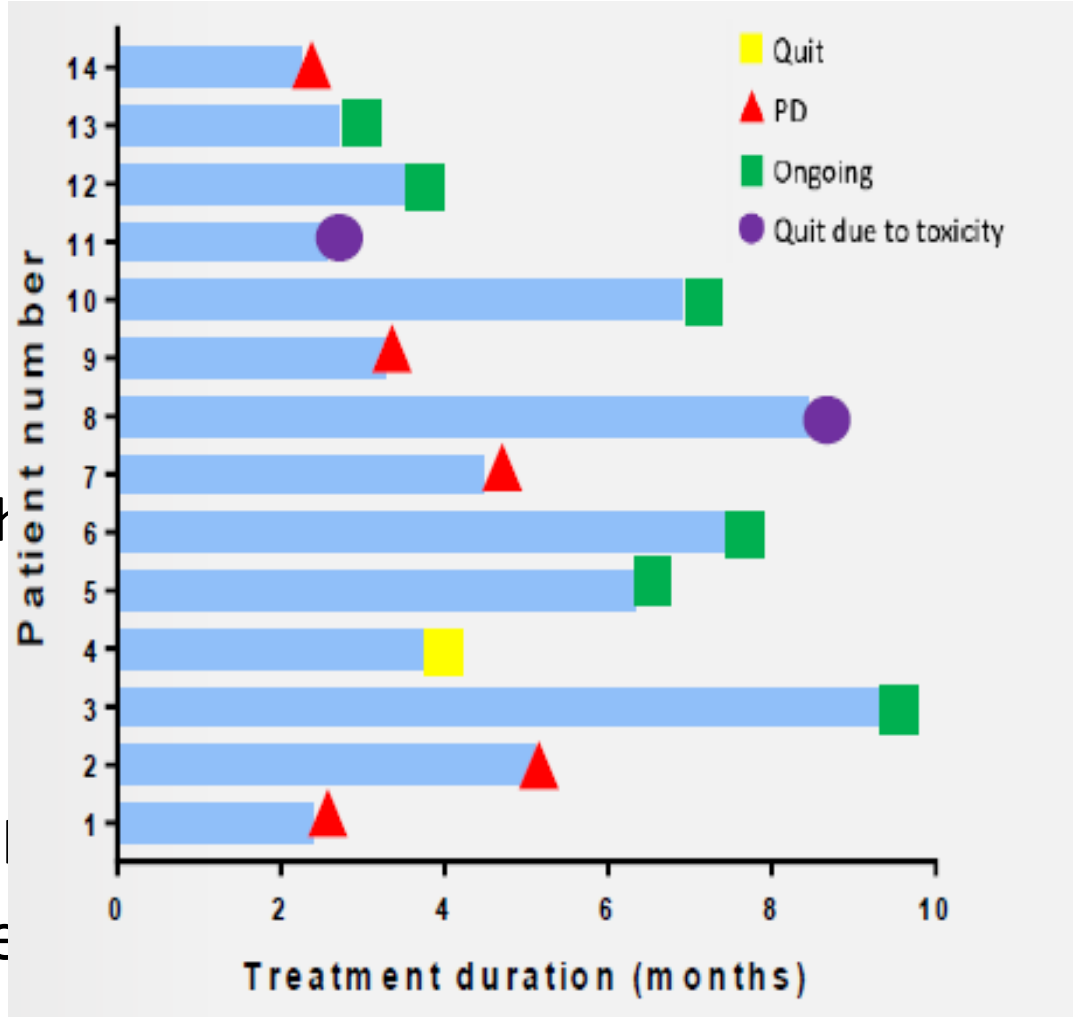
Results

- Sep 2020 to Nov 2021
- N = 16 pts
- In Camrelizumab plus apatinib group,
  - ORR was 66.7% (2/3),
  - DCR was 66.7% (2/3),
  - Median DoR was 2.53 [95% CI 1.4-3.1] month
- In Camrelizumab monotherapy group,
  - ORR was 54.5% (6/11),
  - DCR was 90.9% (10/11),
  - Median DOR was 3.19 [95% CI 1.1-6.9] mont
- Median PFS and OS data were not mature



Side effects -

- Treatment-related adverse events(TRAE) occurring in at least 1% of the patients
- Adverse events that led to the discontinuation of any agent occurred in 1.9% (3/16) of the pts.
- No treatment-related deaths were reported.

TRAE	All treated patients N=16	
	Grade 1–2	Grade 3-4
Reactive cutaneous capillary endothelial proliferation	6(37.5%)	0
Fever	2(12.5%)	0
Hypophysitis	2(12.5%)	1(6.25%)
Hepatic function abnormal	1(6.25%)	1(6.25%)
Rash	1(6.25%)	0
Pneumonitis	2(12.5%)	0

Conclusion

- Camrelizumab monotherapy or plus apatinib showed promising antitumour activity with manageable toxicity profile for PD-L1-positive PSC pts.
- This encourages the clinical practice with ICIs in PSC.

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Thank You !