

KEYNOTE-158

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Primary Endpoint: ORR

ASCO2018

Secondary Endpoint: PFS, OS, duration of response(DOR)

Phase II basket study of 11 cancers

Prior therapy 1-2 regimen: n=85/107(79%)

microsatellite instability-high (MSI-H)
microsatellite-stable (MSS)

MSI-H tumors : 0

MSS tumors : 83(78%)

SCLC
n=107

化学療法既治療
小細胞肺癌患者
進展型小細胞肺癌
・ PD-L1 発現
(TPS \geq 1%)



Positive
PD-L1 n=42
(39%)

Negative
PD-L1 n=50
(47%)

n=107

Pembrolizumab

200mg/kg every 3weeks
24 months or until PD

median
PFS

median
duration of
response

ORR

OR
PD-L1 positive

median
OS

2.0ヶ月

not reached

18.7%
(20/107)

35.7%

9.1ヶ月

PD-L1 negative: 6%

PD-L1 positive :2.1ヶ月
PD-L1 negative:1.9ヶ月

PD-L1 positive :14.6ヶ月
PD-L1 negative:7.7ヶ月

※Conclusions: Pembrolizumab has shown promising antitumor activity and durable responses in advanced SCLC, especially in pts with PD-L1-positive tumors.