ペムブロリズマブ＋CBDCA＋nabPTX療法(21日間/サイクル)　　肺癌

催吐リスク　Moderate　　肺 PEM+CBDCA6/d1

薬剤名	投与経路	投与量		希釈液			点滴時間（分）	投与日(day)
			mg					
			mg					
パロノセトロン	注射	0.75	mg					1
デキサメタゾン	注射	6.6	mg	生食	100	mL	30	1
キイトルーダ	200	mg/bo		生食	100	mL	30	1
アブラキサン	100	mg/m2		生食		mL	30	1，8，15
カルボプラチン	6	AUC		5%糖液	250	mL	60	1
						mL		
						mL		

内服薬

デキサメタゾン　8mg 分2　朝昼食後　day2,3

投与基準等

Ⅱ．投与基準（例：白血球≧2000/mm³、好中球≧1000/mm³）

Toxicity	Hold Treatment For Grade	Timing for Restarting Treatment	Treatment Discontinuation
Diarrhea Colitis	2-3	Toxicity resolves to Grade 0-1	Toxicity does not resolve within 12 weeks of last dose or inability to reduce corticosteroid to 10 mg or less of prednisone or equivalent per day within 12 weeks
	4	Permanently discontinue	Permanently discontinue
AST, ALT, or Increased Bilirubin	2	Toxicity resolves to Grade 0-1	Toxicity does not resolve within 12 weeks of last dose
	3-4	Permanently discontinue (see exception below)*	Permanently discontinue
Type 1 diabetes mellitus (if new onset) or Hyperglycemia	T1DM or 3-4	Hold pembrolizumab for new onset Type 1 diabetes mellitus or Grade 3-4 hyperglycemia associated with evidence of beta cell failure	Resume pembrolizumab when patients are clinically and metabolically stable
Hypophysitis	2-4	Toxicity resolves to Grade 0-1. Therapy with pembrolizumab can be continued while endocrine replacement therapy is instituted	Toxicity does not resolve within 12 weeks of last dose or inability to reduce corticosteroid to 10 mg or less of prednisone or equivalent per day within 12 weeks
Hyperthyroidism	3	Toxicity resolves to Grade 0-1	Toxicity does not resolve within 12 weeks of last dose or inability to reduce corticosteroid to 10 mg or less of prednisone or equivalent per day within 12 weeks
	4	Permanently discontinue	Permanently discontinue
Hypothyroidism		Therapy with pembrolizumab can be continued while thyroid replacement therapy is instituted	Therapy with pembrolizumab can be continued while thyroid replacement therapy is instituted
Infusion Reaction	2*	Toxicity resolves to Grade 0-1	Permanently discontinue if toxicity develops despite adequate premedication
	3-4	Permanently discontinue	Permanently discontinue
Pneumonitis	2	Toxicity resolves to Grade 0-1	Toxicity does not resolve within 12 weeks of last dose or inability to reduce corticosteroid to 10 mg or less of prednisone or equivalent per day within 12 weeks
	3-4	Permanently discontinue	Permanently discontinue
Renal Failure or Nephritis	2	Toxicity resolves to Grade 0-1	Toxicity does not resolve within 12 weeks of last dose or inability to reduce corticosteroid to 10 mg or less of prednisone or equivalent per day within 12 weeks
	3-4	Permanently discontinue	Permanently discontinue
All Other Drug-Related Toxicity*	3 or Severe	Toxicity resolves to Grade 0-1	Toxicity does not resolve within 12 weeks of last dose or inability to reduce corticosteroid to 10 mg or less of prednisone or equivalent per day within 12 weeks
	4	Permanently discontinue	Permanently discontinue

Ⅲ. 減量基準 (例:Grade3 以上の好中球減少時、次回より投与量を80%に減量)

Ⅳ. 重大な副作用 (例:好中球減少 Grade3 以上37. 5%)

<切除不能な進行・再発の非小細胞肺癌>

※ 併用投与時 国際共同第Ⅱ相試験(KEYNOTE-189試験)で、本剤200mgを3週間間隔で投与された安全性解析対象例405例中372例(91.9%)(日本人4例中3例を含む)に副作用が認められた。主な副作用(20%以上)は、悪心187例(46.2%)、貧血154例(38.0%)、疲労134例(33.1%)、好中球減少症101例(24.9%)及び食欲減退84例(20.7%)であった。
国際共同第Ⅲ相試験(KEYNOTE-407試験)で、本剤200mgを3週間間隔で投与された安全性解析対象例278例中265例(95.3%)(日本人22例中22例を含む)に副作用が認められた。主な副作用(20%以上)は、脱毛症126例(45.3%)、貧血123例(44.2%)、好中球減少症97例(34.9%)、悪心85例(30.6%)、血小板減少症81例(29.1%)及び下痢61例(21.9%)であった。(承認時)

添付参考資料(文献・ガイドライン・治験計画書・研究計画書)

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