

# Summary of Concurrent Chemoradiotherapy for locally advanced NPC

Data from



**T. OHNO, NIRS**

# Dose Escalation Schedule

## Dose Level:

**Level 1: Cisplatin 30mg/m<sup>2</sup>/week**

**Level 2: Cisplatin 40mg/m<sup>2</sup>/week**

## Dose Limiting Toxicities (DLT):

- 1. Grade 4 hematological toxicities**
- 2. Grade 4 toxicities in skin, mucosa and salivary**
- 3. Grade 3 non-hematological toxicities except 2**
- 4. Interruption of radiotherapy  $\geq$  2 weeks**
- 5. Interruption of chemotherapy  $\geq$  3 cycles**

# Registered Cases



IDN



PHL



THA



CHN



MYS

Level 1  
(30mg/m<sup>2</sup>)

3

3

2

16★

2★

Level 2  
(40mg/m<sup>2</sup>)

3

-

-

0

1★★★

Total No.

6

3

2

16

3

★ 25mg/m<sup>2</sup>

★★★ 35mg/m<sup>2</sup> & 7cycles

# Compliance of Chemotherapy

					
	<b>IDN</b>	<b>PHL</b>	<b>THA</b>	<b>CHN</b>	<b>MYS</b>
<b>Cycles</b>	4 5 6	4 5 6	4 5 6	4 5 6	4 5 6 7
<b>Level 1 (30mg/m<sup>2</sup>)</b>	0 0 3	0 0 3	0 0 2	?	0 1 1 
<b>Level 2 (40mg/m<sup>2</sup>)</b>	0 0 3	-	-	?	0 0 0 1  
<b>Total Pts.</b>	6	3	2	?	3

 25mg/m<sup>2</sup>

  35mg/m<sup>2</sup> & 7cycles

# Grade 4 Hematological Toxicity

	 IDN	 PHL	 THA	 CHN	 MYS
Level 1 (30mg/m <sup>2</sup> )	0/3	0/3	0/2	?/?	0/2 ★
Level 2 (40mg/m <sup>2</sup> )	0/3	-	-	-	0/1 ★★
Total No.	0/6	0/3	0/2	?/?	0/3

★ 25mg/m<sup>2</sup>

★★ 35mg/m<sup>2</sup> & 7cycles

# Grade 4 Toxicity in Skin, Mucosa and Salivary

	 IDN	 PHL	 THA	 CHN	 MYS
Level 1 (30mg/m <sup>2</sup> )	0/3	0/3	0/2	?/?	0/2 ★
Level 2 (40mg/m <sup>2</sup> )	0/3	-	-	-	0/1 ★★
Total No.	0/6	0/3	0/2	?/?	0/3

★ 25mg/m<sup>2</sup>

★★ 35mg/m<sup>2</sup> & 7cycles

# Grade 3-4 Toxicity in UGI, Weight and Fatigue

	 IDN	 PHL	 THA	 CHN	 MYS
Level 1 (30mg/m <sup>2</sup> )	0/3	0/3	0/2	?/?	0/2 ★
Level 2 (40mg/m <sup>2</sup> )	0/3	-	-	-	0/1 ★★
Total No.	0/6	0/3	0/2	?/?	0/3

★ 25mg/m<sup>2</sup>

★★ 35mg/m<sup>2</sup> & 7cycles

# Summary & Discussion

- **Five countries have started the phase I study of concurrent chemoradiotherapy for locally advanced NPC.**



IDN

...Phase I study finished.



PHL



THA

... Phase I study on going.



MYS



CHN

- **The remain 3 countries have not yet started.**



KOR



VNM



JPN



# Summary & Discussion

**From the present results, weekly administration of Cisplatin at 30mg/m<sup>2</sup> seems to be safe. We also need to confirm the toxicity at 40mg/m<sup>2</sup>. After determination of the dose of Cisplatin, starting phase II study will be recommended.**

**Phase I study  
(30mg → 40mg)**



**Phase II study  
(details will be discussed)**



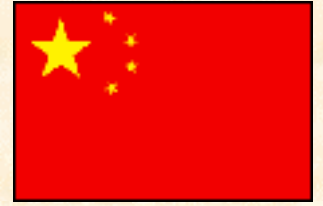
IDN



KOR



THA



CHN



JPN



PHL



MYS



VNM

# Hematological Toxicity

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Level	#Pts	WBC				Neutro				Hb				PLT			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4

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1

2

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\* Usage of G-CSF

# Non-hematological Toxicity ( )

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Level	#Pts	Skin				Mucositis				Pain				Salivary			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4

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1

2

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# Non-hematological Toxicity

( )

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Level	#Pts	Nausea / Vomiting				Weight loss				Fatigue				#cycle			
		1	2	3	4	1	2	3	4	1	2	3	4	6	5	4	3

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1

2

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