

Nimotuzumab in GI Cancer

Updates on the current evidences

Innokeys

CIMaHer Product Profile

CIMaHer™
nimotuzumab 50 mg

Brand Name	CIMaHer
Composition	Vial contain: Nimotuzumab 50 mg
Dosage Form	Injection
Manufacturer	Centro De Inmunologia Molecular (CIM), La Habana, Cuba
Mechanism of Action	Anti EGFR

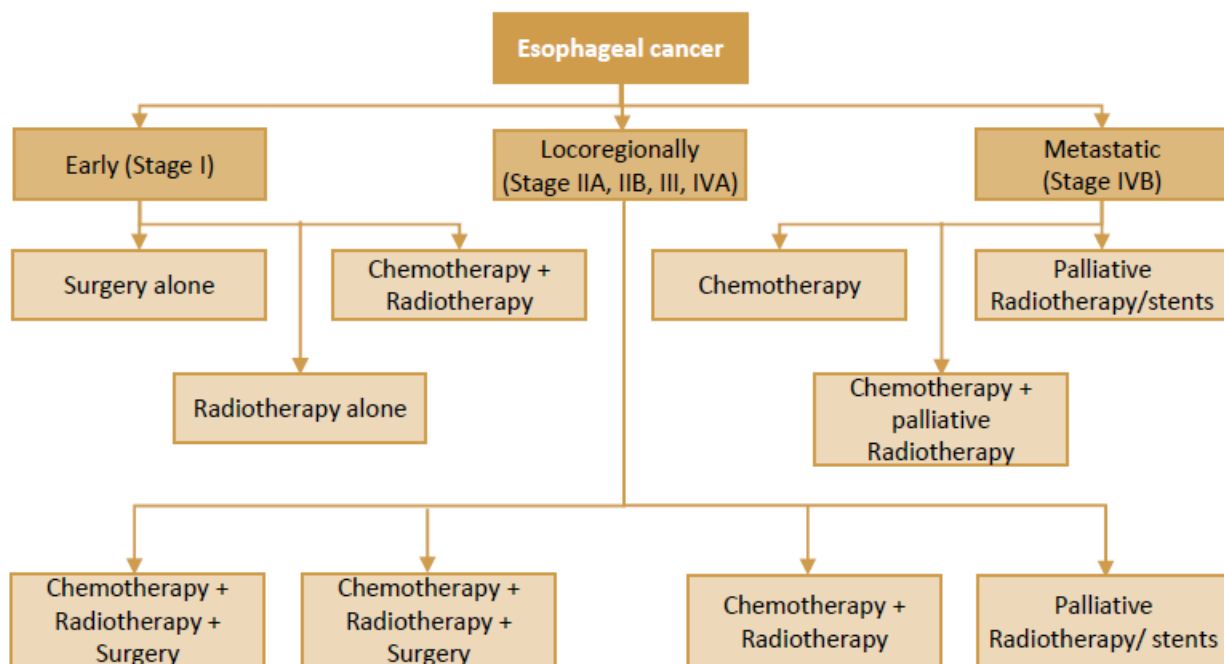


Nimotuzumab
(Indonesia)

Esophageal Cancer

Current treatment options & nimotuzumab related clinical trials

Current treatment options (all Stages)

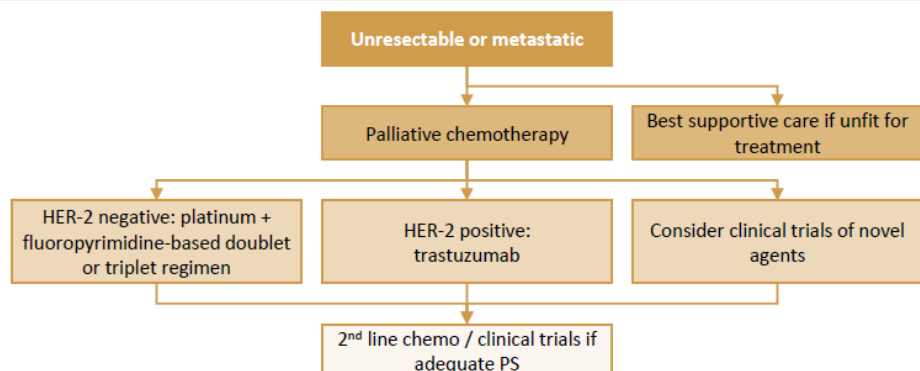


Clinical trials with nimotuzumab related to esophageal cancer

Title	Country	Type	Primary endpoint	Population	Status
nimotuzumab + Paclitaxel + Cisplatin <i>BPL-IST-ESO-057</i>	China	Phase III (N=504)	OS	1 st line treatment for patients with locally advanced metastatic esophageal squamous cell carcinomas (randomized 1:1)	Ongoing with 20 out of 504 patients already included
nimotuzumab + concurrent chemoradiotherapy <i>NxCel1311</i>	China	Phase III (N=200)	OS	Locally advanced esophageal squamous cell carcinomas (randomized 1:1)	Ongoing with 36 out of 200 patients already included
<i>nimotuzumab combined with radiation therapy and chemotherapy</i>	Brazil	Phase II (N=107)	ECRR	<i>locally advanced and inoperable esophageal tumors with no previous treatment of the disease (randomized)</i>	20 patients of 54 control arm (37.04%) 95% CI [24.29% – 51.26%] 33 patients of 53 nimotuzumab arm (62.26%) 95% CI 47.89% – 75.21%] (p=0.0157)
<i>Nimotuzumab – concurrent chemoradiotherapy</i>	Japan	Phase Ib (N=10)	tolerability, safety, efficacy, and PK	<i>Stage II, III, and IV esophageal cancer</i>	Completed Tolerable & Effective PFS: 13.9 months 1 year survival 75% 3 year survival 37.5%

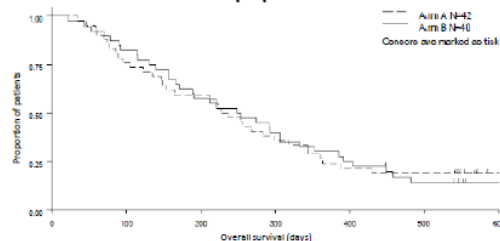
Gastric Cancer

Current treatment options (unresectable or metastatic)

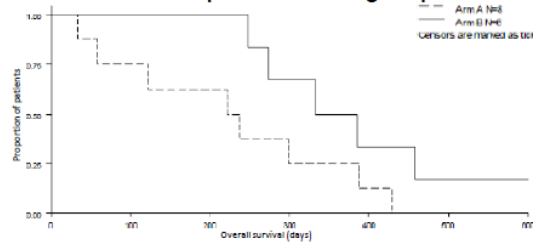


Key results

Overall survival in all population



Overall survival of patients with high expression of EGFR



- Nimotuzumab has higher efficacy in patients with advanced gastric cancer with high expression of EGFR

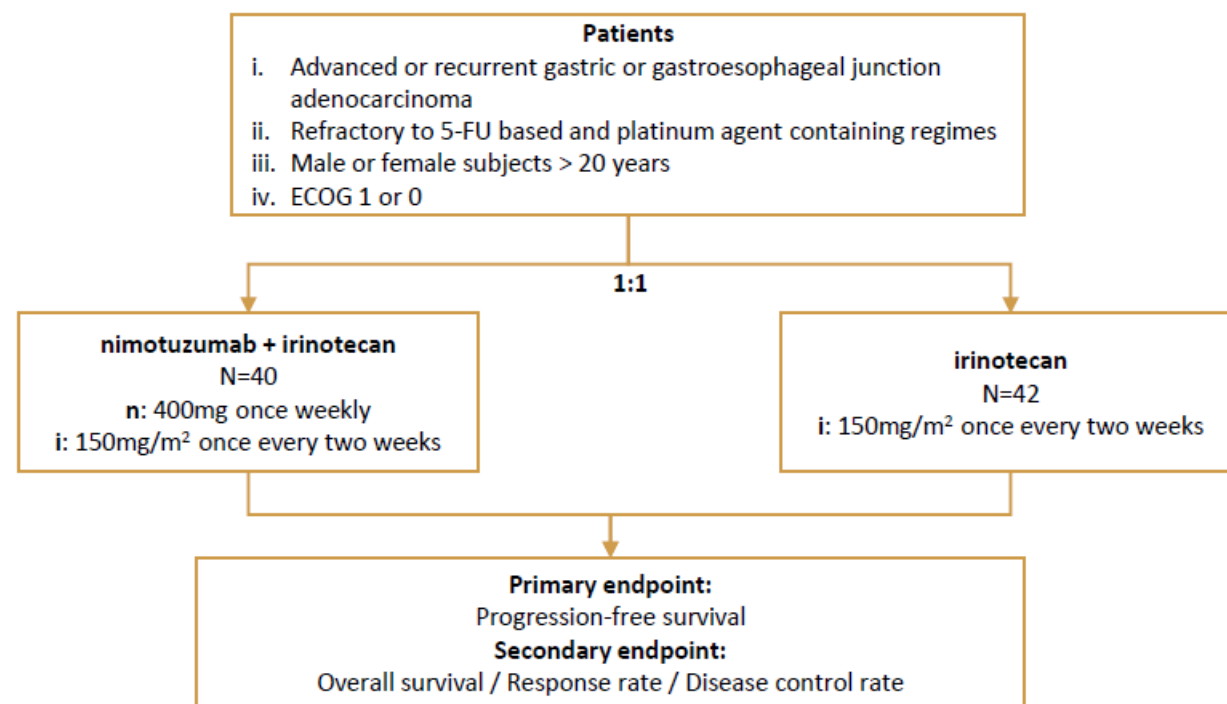
Population	P-value	HR	nimotuzumab + Irinotecan	Irinotecan
Patients with EGFR +2+3	0.0944	0.369	OS: 358.5 days / N: 6	OS: 229.5 days / N: 8

Results to date

Study outline

Completed Phase II study: DE766-A-J201 in Japan

- A Phase II open-label, randomized study of nimotuzumab plus irinotecan compared to irinotecan alone in advanced or recurrent gastric cancer refractory to 5-FU and platinum-containing regimens



Efficacy and safety

Nimotuzumab

Trial	Trial design	Primary endpoint	Population	Control group	Treatment group	P-value	HR
nimotuzumab + irinotecan vs irinotecan <i>Phase II study</i>	Phase II (N=83)	PFS	AGC who previously received platinum- and FU-containing chemotherapy (All population)	2.3 mo	2.86 mo	0.691	0.86
			AGC (EGFR overexpression) (N = 14)	1.96 mo	3.95 mo	0.1293	0.341
		Secondary endpoint: OS	AGC (All population)	9.41 mo	9.9 mo	0.9778	0.994
			AGC (EGFR overexpression) (N = 14)	7.6 mo	11.9 mo	0.094	0.369

Other trials

Trial	Trial design	Primary endpoint	Population	Control group	Treatment group	P-value	HR
paclitaxel vs irinotecan <i>WJOG 4007</i>	Phase III (N=223)	OS	AGC who previously received platinum- and FU-containing chemotherapy	8.4 mo	9.5 mo	0.38	1.13
docetaxel + active symptom control vs active symptom control <i>Cougar-02</i>	Phase III (N=168)	OS	AGC who previously received platinum- and FU-containing chemotherapy	5.2 mo	3.6 mo	0.1	0.67
ramucirumab + paclitaxel vs paclitaxel + placebo <i>RAINBOW study</i>	Phase III (N=665)	OS	AGC who previously received platinum- and FU-containing chemotherapy	7.4 mo	9.6 mo	0.017	0.81

Safety

Toxicities	paclitaxel vs irinotecan <i>WJOG 4007</i>		ramucirumab + paclitaxel <i>RAINBOW study</i>		nimotuzumab + irinotecan <i>Phase II study</i>	
	paclitaxel arm (N=111)	irinotecan arm (N=112)	placebo + paclitaxel arm (N=329)	ramucirumab + paclitaxel arm (N=327)	irinotecan arm (N=43)	nimotuzumab + irinotecan arm (N=40)
AEs grade III-IV						
Nausea	1.9%	4.5%	2%	3%	9.5%	15.0%
Neutropenia	28.7%	39.1%	19%	41%	38.1%	45%
Leukopenia	20.4%	19.1%	7%	18%	9.5%	15%
Anemia	21%	30%	10%	9%	7.1%	12.5%

Thank you
