

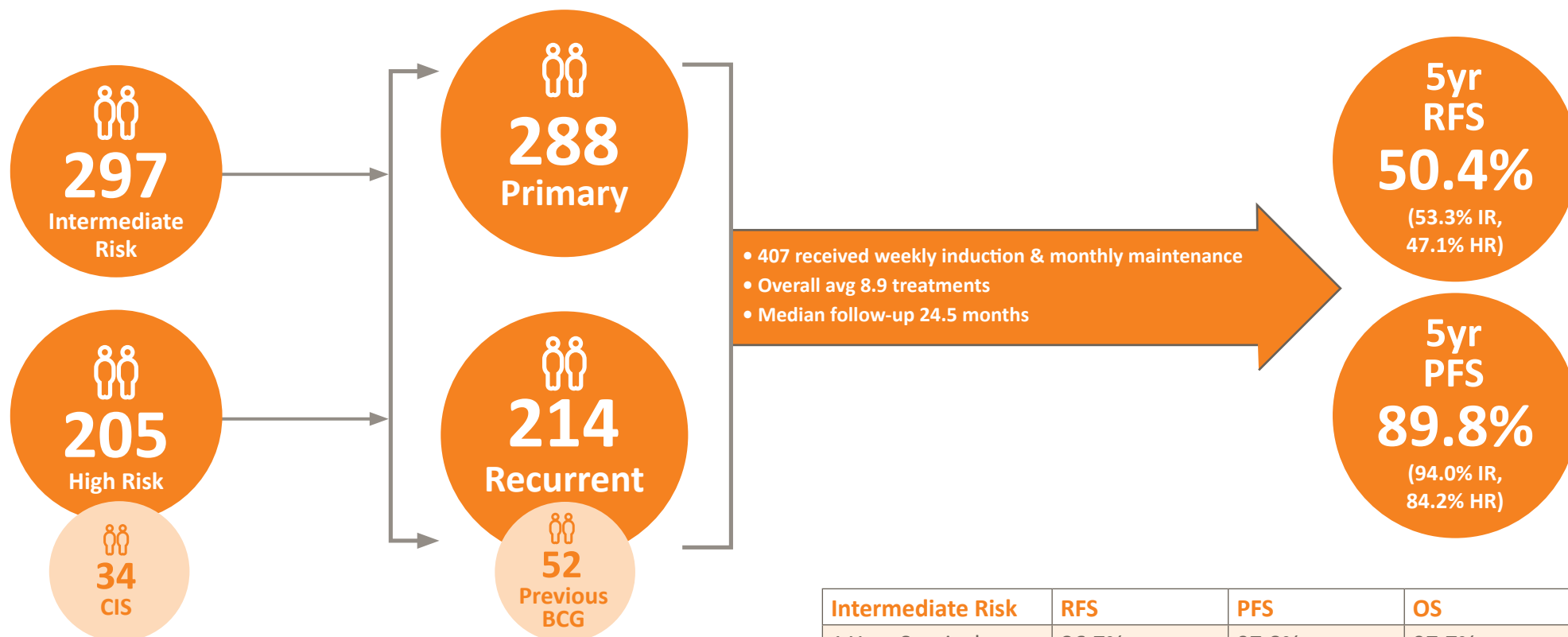
## Visual Summary of: Long-Term Experience with Hyperthermic Chemotherapy, (HIVEC®) Using Mitomycin-C in Patients with Non-Muscle Invasive Bladder Cancer in Spain.

Javier C. Angulo, Ana Plata, Felix Guerrero-Ramos et al.



### HIVEC-E Spain

A prospective observational trial in 9 academic centres in Spain treated with HIVEC® with 40mg MMC given adjuvantly for intermediate and high risk NMIBC.



**Conclusions:** HIVEC® through MMC using COMBAT BRS is an efficacious and well-tolerated alternative for patients with intermediate and high-risk NMIBC. A maintenance schedule should be recommended as the duration of treatment is the most important independent prognostic factor.

Intermediate Risk	RFS	PFS	OS
1 Year Survival	86.7%	97.8%	97.7%
2 Year Survival	75.1%	96.0%	92.7%
5 Year Survival	53.3%	94.0%	74.3%
High Risk			
1 Year Survival	80.3%	94.0%	94.1%
2 Year Survival	64.9%	86.5%	88.1%
5 Year Survival	47.1%	84.2%	60.1%

## Top Bullets Guide

### RFS

- RFS is increased by longer duration of treatment (**p=0.0002**)
- RFS is increased by use of maintenance therapy (**p=0.0007**)
  - The Kaplan-Meier Survival Curve shows about 20% increase

### PFS

- PFS is increased by use of maintenance therapy (**p=.0016**)
  - The Kaplan-Meier Survival Curve shows about 15% increase

### Overall Survival

- Treatment Duration > 4 months is an independent predictor of survival (**p=0.0211**)

### Tolerability & Safety

- 406 pts (68.6%) had no AEs.
- Only 16 pts (2.7%) Grade 3 or worse.

### Conclusion From The Paper

HIVEC with MMC using COMBAT BRS is an efficacious and well tolerated alternative for patients with intermediate and high-risk NMIBC. A maintenance schedule should be recommended as the duration of treatment is the most important independent prognostic factor.



### Guy's Guidance.

#### Existing Customers

- Maintenance is proven to be important for both IR and HR.
  - 6+9 treatments is more than 6+0.

#### New Customers

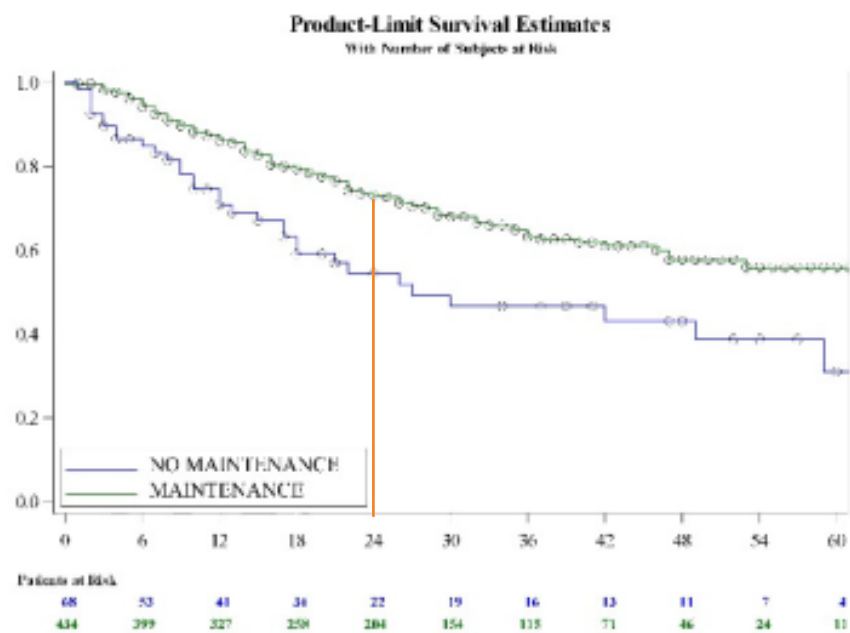
- Drs think 70% IR RFS @ 2yrs is good. We're 75% in IR, and almost 80% across the whole group, including the HR patients, when maintenance is used.
- In High Risk, they will look for a PFS of 80%+, we're 86% and higher still when maintenance is used.

### How we compare with "expected recurrence and progression rates" using BCG –

	Risk groups	24-month DFS	24-month PFS
HIVEC Inductions + Maintenance for more than 4 months	Intermediate	>75%	>96%
	High	>65%	>86%
The figures above include patients with and without maintenance. The group that received maintenance would have a considerably higher RFS & PFS.			
EORTC*	Intermediate-Chemo	60%	95%
	Intermediate-BCG (1 year)	70%	96%

\*EORTC - European Organisation for Research and Treatment of Cancer

## Recurrence-Free Survival for the Whole Cohort, including Intermediate and High Risk



## Progression-Free Survival Whole Cohort, including Intermediate and High Risk

