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### INTRODUCTION

- Controlled ovarian stimulation is a key step in vitro fertilization (IVF/ICSI) procedure
- The individual response to COS depends on several factors
- The relationship between serum AMH levels and the number of retrievable oocytes has been established. However, in practice the dose of gonadotropins is not always adjusted linearly to the level of AMH
- It is crucial to determine the factors influencing the initial dose of gonadotropins used during COS cycle

### STUDY DESIGN & METHODS :

- French non-interventional, longitudinal, prospective, multicenter, cohort study conducted on infertile women initiating HP-hMG 600 IU/mL\* for COS within their first IVF/ICSI cycle.
- 340 subjects were enrolled in one year aged between 18 and 42 years old
- 25 ART public and private centers involved all over France
- Data collected prospectively from patients' medical files through routine follow-up visits scheduled by the investigator from COS initiation up to 10-11 weeks after embryo transfer.

**Primary objective:** evaluate the relationship between AMH level and the initial dose of HP-hMG

### RESULTS

From October 2016 to December 2017, 297 patients were enrolled in the study, 235 of whom compose the per protocol population .

Patients profile	N = 235
AGE (year), Mean(SD)	32,5 (4,6)
BMI (kg/m <sup>2</sup> ), Mean(SD)	24,3 (4,8)
Smokers, n (%)	38 (16,2)
Primary Infertility, n (%)	140 (59,6)
Infertility anteriority(year), Mean(SD)	3,1 (1,9)
ICSI, n (%)	136 (57,9)
Antral follicular count (AFC) <8, n (%)	23 (12,3)
AMH (ng/mL), Mean(SD)	2,3 (1,7)
AMH <1,1 ng/mL, n (%)	54 (23,0)

AMH, anti-müllerian hormone; BMI, body mass index

Correlation between serum AMH levels and Initial dose of HP-hMG 600IU/mL		N=235
Initial dose of HP-hMG, IU/mL	Mean (SD)	233,8 (73,0)
	Median (Q1 ; Q3)	225 (150 ; 300)
	Min ; Max	113 ; 450
Serum AMH level, ng/mL	Mean (SD)	2,3 (1,7)
	Median (Q1 ; Q3)	2,0 (1,1 ; 3,0)
	Min ; Max	0 ; 11
Correlation analysis	Spearman Coefficient	-0,633
	p-value	<0,001

AMH, anti-müllerian hormone; Q1, first quartile; Q3, third quartile;

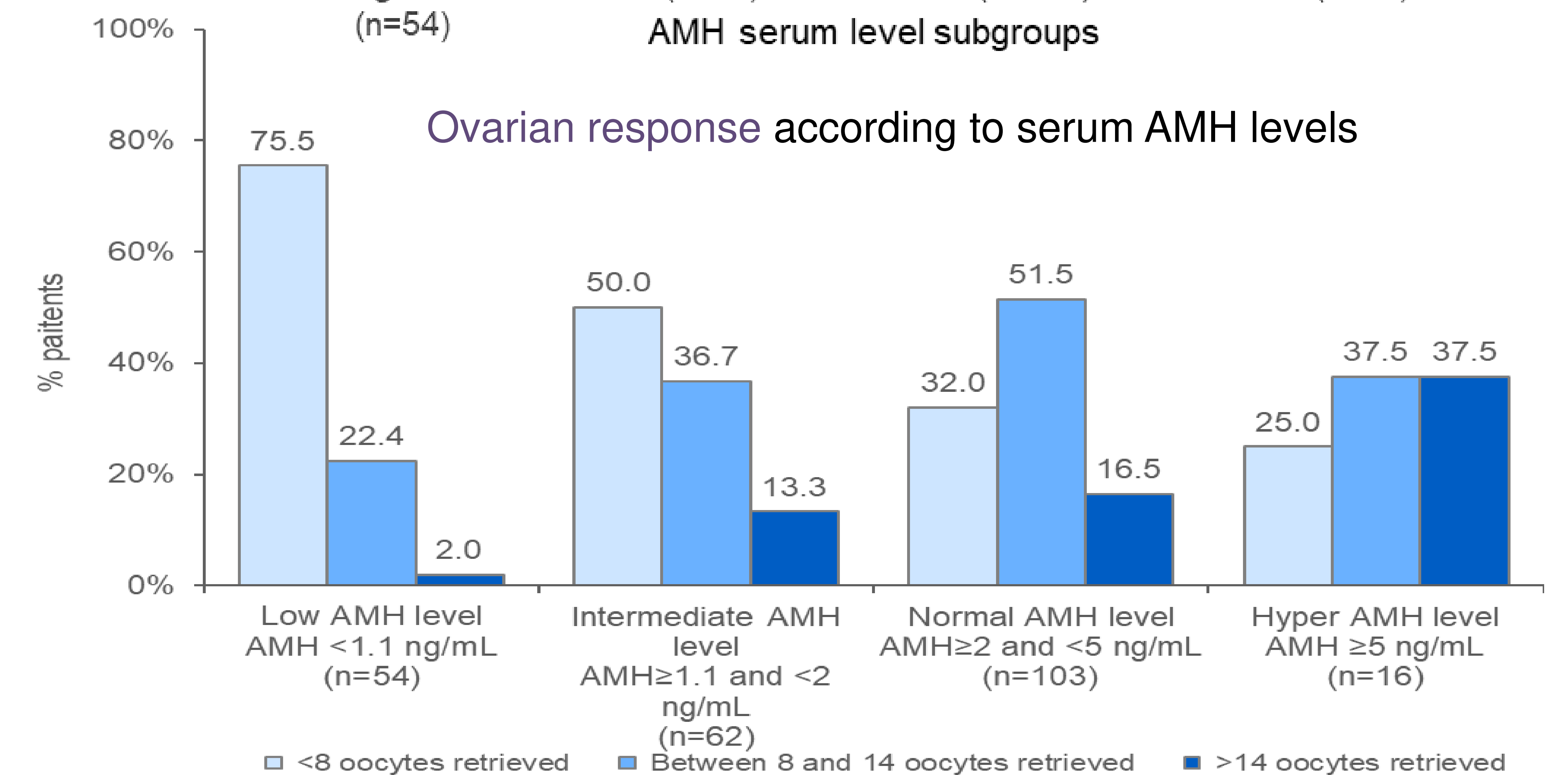
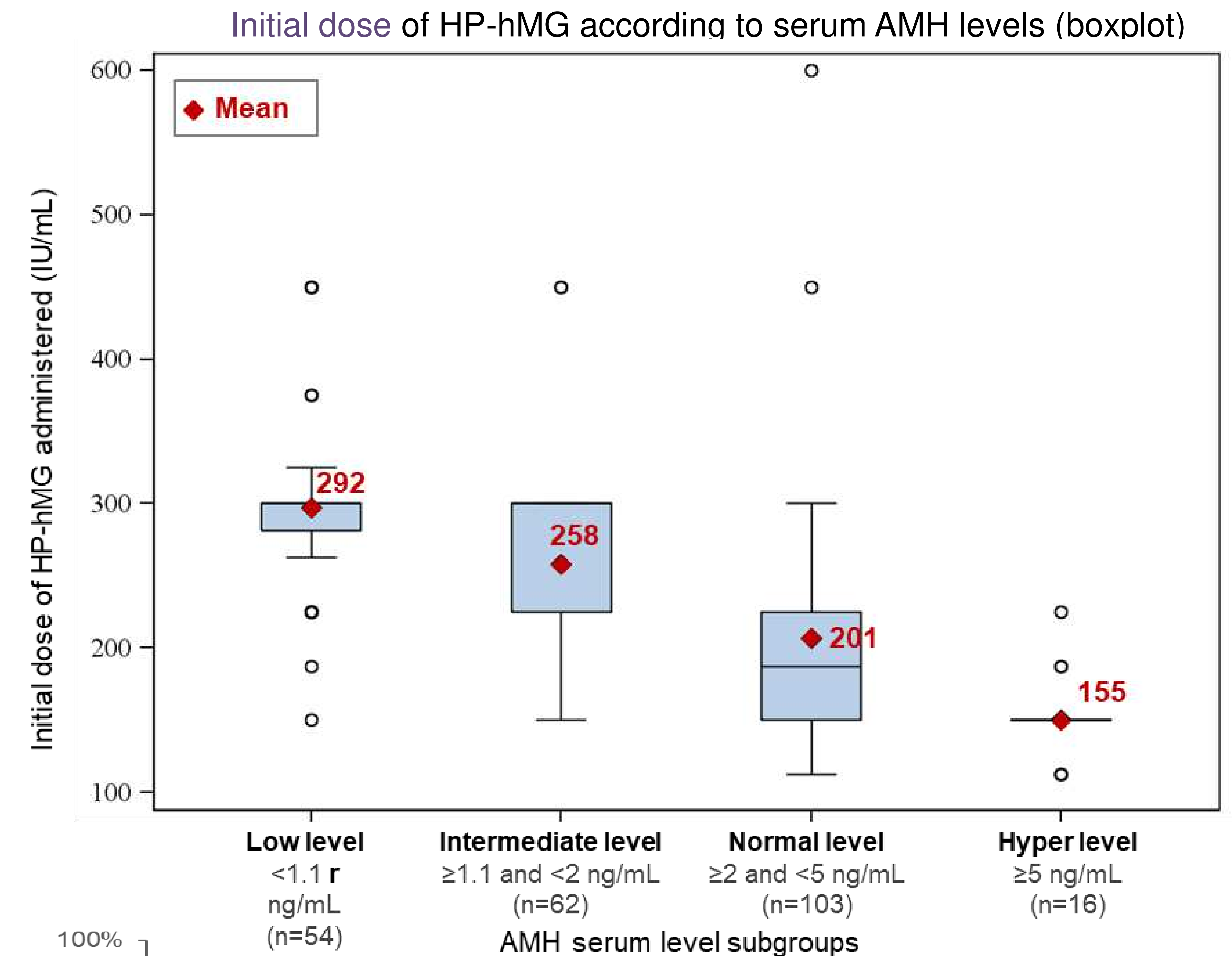
Terms of HP-hMG 600 UI/mL	N = 235
Antagonist protocol, n (%)	198 (84,2)
Oestradiol pre-treatment, n (%)	146 (62,2)
Initiale dose of HP-hMG (IU/mL), mean (SD)	233 (73)
Dose reduction, n (%)	55 (23,4)
Dose increase, n (%)	50 (21,3)
Total dose of HP-hMG (IU/mL), mean (SD)	2473 (971)
Treatment duration (day), mean (SD)	9,5 (1,9)

### CONCLUSION

- Impact on AMH level on the initial dose of HP-hMG  
*The lower the AMH level, the higher the initial dose of HP-hMG prescribed*
- Impact on AMH level and weight on the total dose of HP-hMG  
*The higher the weight, the higher the total dose of HP-hMG prescribed*
- 94% of subjects who achieved triggering have obtained embryo(s)
- Top quality embryo obtained in 52% of subjects who achieved triggering
- Overall pregnancy rate of 29%
- Pregnancy rate of 37% in subjects who achieved embryo transfer

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### RESULTS



### Safety results

- No safety information or information with potential impact in the benefit-risk assessment has arisen during the study period
- <10% of subjects reported 31 expected AE related to Menopur®
- Treatment-related AE were mainly non serious AE (28 AE; 22 patients)
- 3 subjects (0.8%) experienced ovarian hyperstimulation that led to hospitalization