

Cost-consequence model comparing the originator r-hFSH-alfa and its biosimilar for ≤4 complete ovarian stimulation cycles during Assisted Reproductive Technology treatment in Spain, France and Germany

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CONCLUSIONS

Originator r-hFSH-alfa vs Biosimilars



Higher CLBR



Lower costs per live birth



Shorter time to live birth

- Starting and continuing OS with originator r-hFSH-alfa may save time and costs in achieving LB versus biosimilars.
- Authors recommend considering the prioritization of originator r-hFSH-alfa in ART treatments based on these findings.
- This change could set a new standard in fertility therapy, improving patient outcomes and access to effective treatments.



INTRODUCTION

- Recent studies show that originator recombinant human follicle-stimulating hormone-alfa (r-hFSH-alfa) is associated with higher cumulative live birth rates (CLBR) than biosimilars, which leads to reduced costs per live birth (LB).^{1,2,3}
- With the increasing demand of fertility services, it is imperative to assess the cost-effectiveness of Assisted Reproductive Technology (ART) treatments in European public systems.
- Evidence regarding the most cost-effective treatment pathway is limited to the first or second ovarian stimulation (OS) cycles^{1,2}. However, most women undergo multiple OS cycles.^{3,4}



OBJECTIVES

To evaluate the clinical and economic outcomes of initiating OS with either the originator r-hFSH-alfa or its biosimilars and consider the implications of continuing or switching treatments over multiple (≤4) OS cycles.



METHODS

- A decision-tree model assessed costs and outcomes (CLBR, total treatment costs, time to LB, costs per LB) comparing originator r-hFSH-alfa versus biosimilars, using clinical data (pregnancy rate, LBR, miscarriage rate) from a recent RWE study⁵ and a meta-analysis⁶, and cost data (stimulation costs, drug costs, embryo transfer and birth/miscarriage costs) from Spain, France and Germany⁷ (**Figure 1**).
- The model considered four complete OS cycles (leading to ovarian pick up), each with one fresh and up to three frozen/thawed embryo transfers.
- Treatment started with either originator r-hFSH-alfa or biosimilar.
- If no live birth occurred, women either continued with frozen embryo transfer or initiated a new OS cycle.
- Outcomes were explored in 2 base-case scenarios (4 OS cycles with either originator r-hFSH-alfa or biosimilar) and 6 switching scenarios (treatment was switched after the 1st, 2nd, or 3rd stimulation cycle without a live birth) (**Figure 1**).
- Model structure and assumptions were validated.

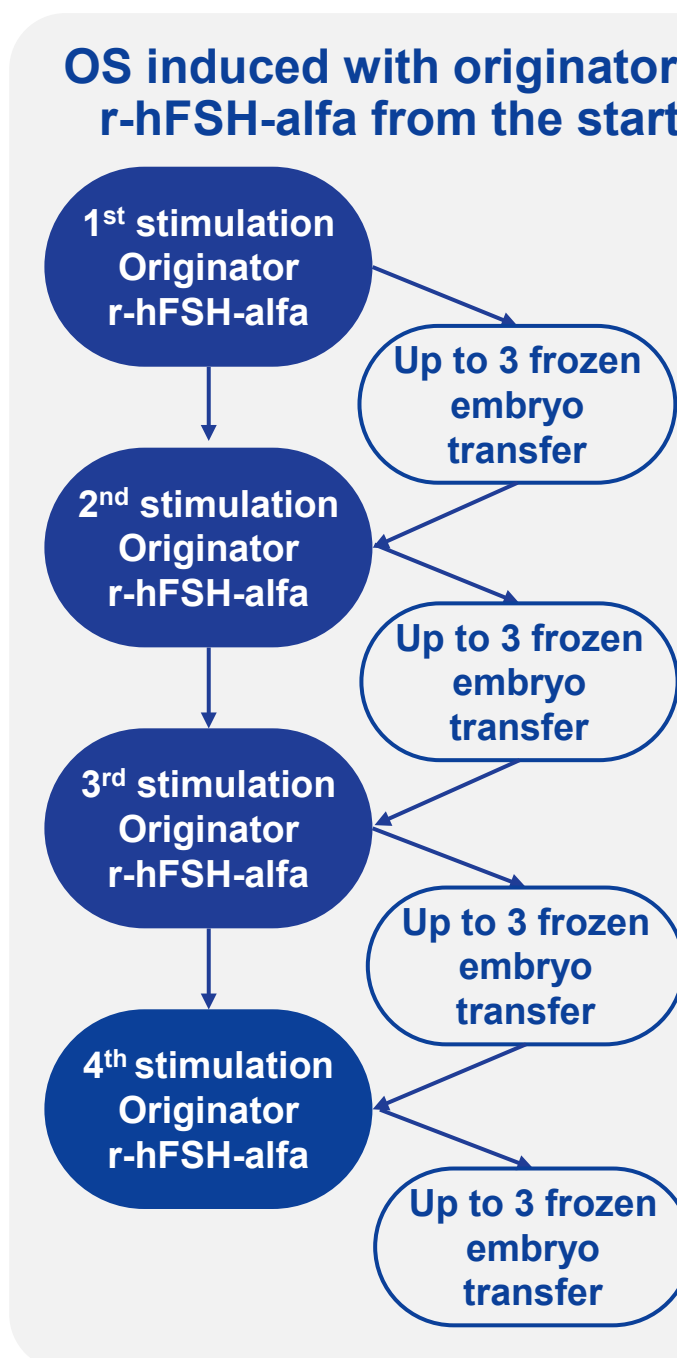


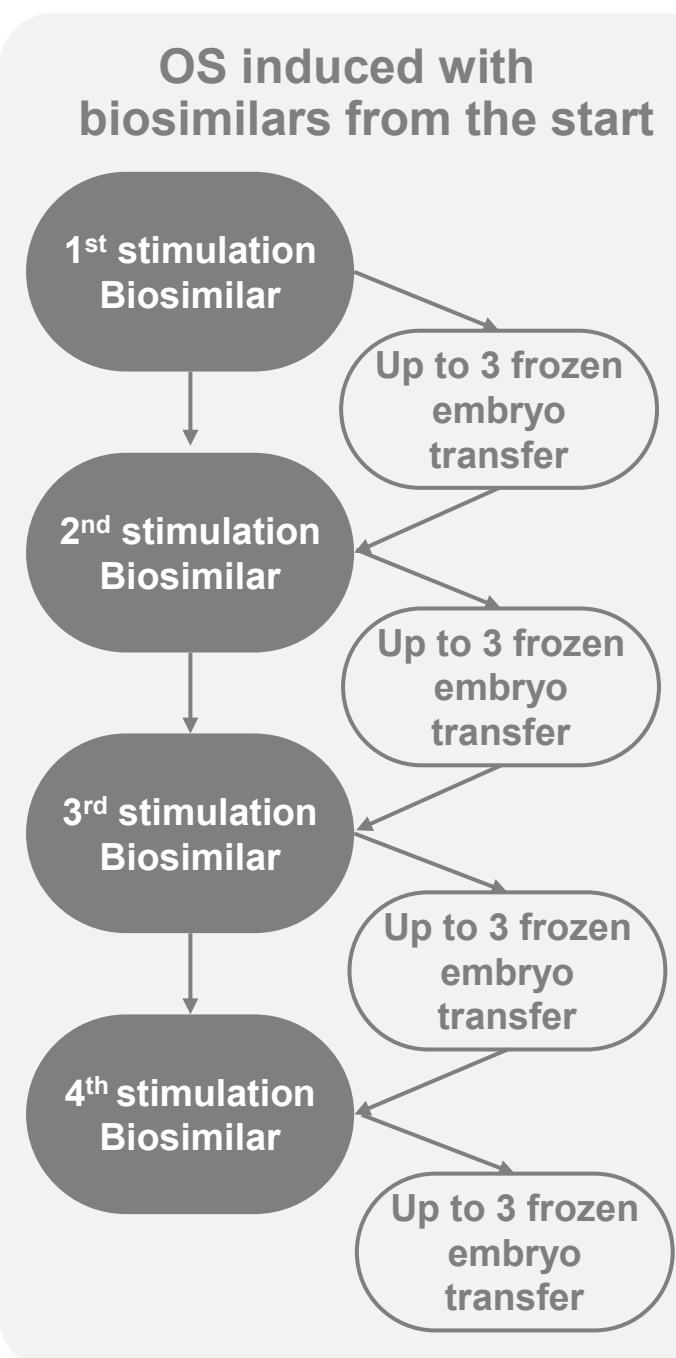
Figure 1. Model structure

Six different scenarios

where women switch from Originator r-hFSH-alfa to biosimilar and vice versa

Switch to biosimilars after no live birth in the 1st or 2nd or 3rd OS with Originator r-FSH-alfa

Switch to Originator r-hFSH-alfa after no live birth in the 1st or 2nd or 3rd OS with biosimilars



RESULTS

- The base-case analysis demonstrated that treatment with originator r-hFSH-alfa achieved a higher CLBR of 58.2% compared to 50.8% with biosimilars (**Table 1**).
- Base case cost-effectiveness results show that “originator r-hFSH-alfa only” dominates “biosimilars only” in Spain and France, being less costly and more effective. (**Table 1** and **Figure 2**).
- In the German setting, the incremental cost-effectiveness ratio (ICER) of “originator r-hFSH-alfa only” vs “biosimilars only” was €778 per live birth in base-case scenario (**Figure 3**). In the switching scenario analyses starting with biosimilars, the ICER was €3,125 for switching to originator r-hFSH-alfa after the third cycle and €3,617 for switching after the first cycle (**Figure 3**).
- Originator r-hFSH-alfa was also associated with a shorter time to live birth (936 days vs 980 days).

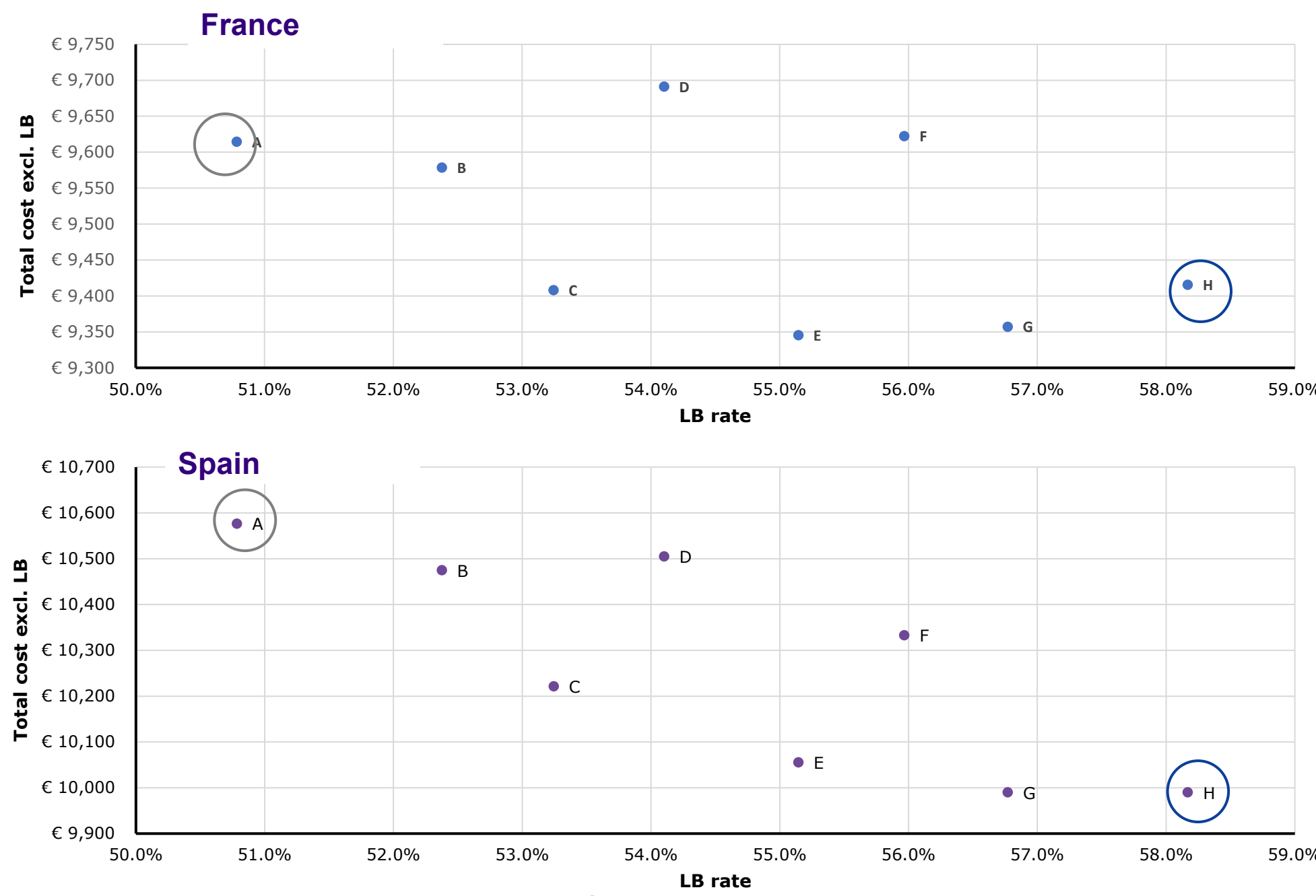
Table 1. Base Case results: LBR, total treatment costs (excl. costs for pregnancy and LB)

	LBR		Costs Germany		Costs France		Costs Spain	
	Originator r-hFSH-alfa	Biosimilar	Originator r-hFSH-alfa	Biosimilar	Originator r-hFSH-alfa	Biosimilar	Originator r-hFSH-alfa	Biosimilar
1st stimulation, cumulatively	23.6%	19.6%	€ 3,440	€ 3,231	€ 3,274	€ 3,158	€ 3,474	€ 3,474
2nd stimulation, cumulatively	15.2%	13.3%	€ 2,627	€ 2,597	€ 2,500	€ 2,538	€ 2,653	€ 2,793
3rd stimulation, cumulatively	11.1%	10.1%	€ 2,103	€ 2,167	€ 2,002	€ 2,118	€ 2,124	€ 2,330
4th stimulation, cumulatively	8.2%	7.8%	€ 1,722	€ 1,841	€ 1,639	€ 1,800	€ 1,739	€ 1,980
Cumulative results	58.2	50.8	€ 9,892.97	€ 9,836	€ 9,416	€ 9,614	€ 9,990	€ 10,577

Costs per live birth across all markets after four cumulative OS were lower with originator r-hFSH-alfa than biosimilar

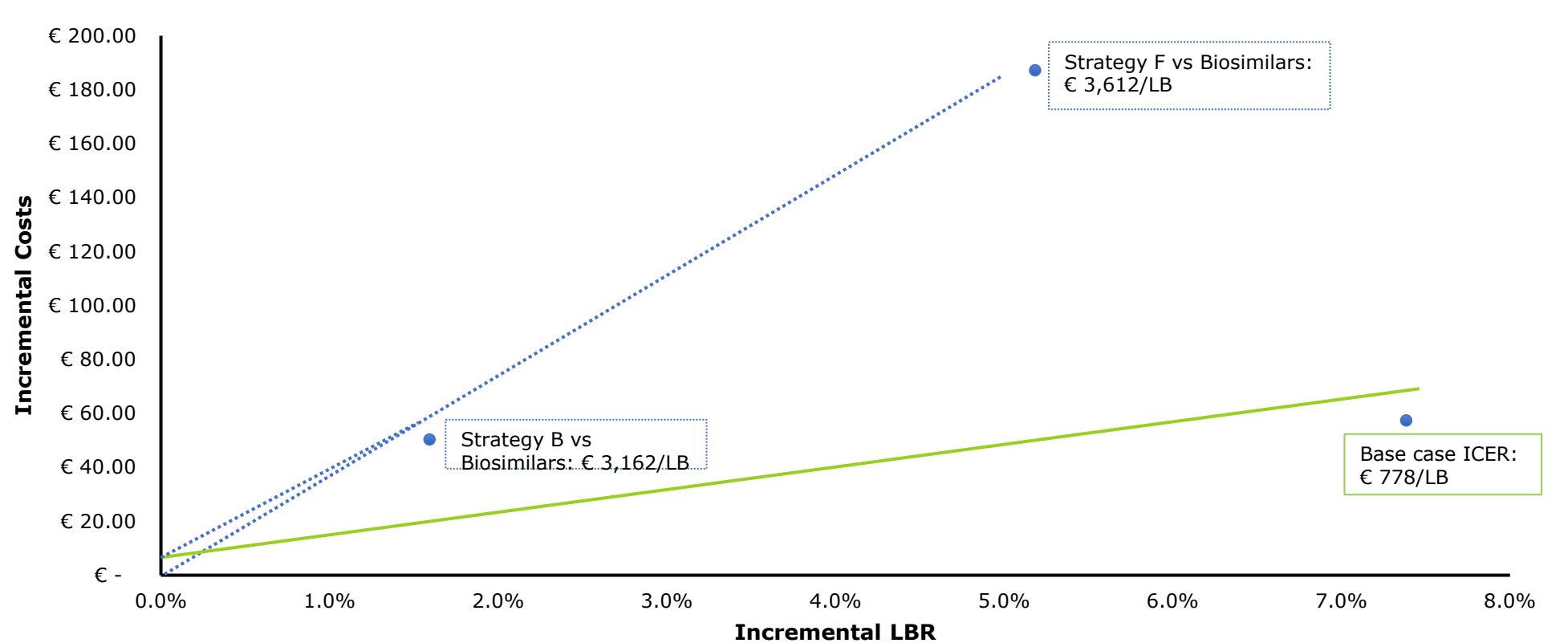
France €16,187 vs €18,932
Spain €17,174 vs €20,828
Germany €17,007 vs €19,367

Figure 2. Scenario analyses (France and Spain)



(A) Biosimilars only
(B) Switch to Originator r-hFSH-alfa after 3rd OS
(C) Switch to Biosimilars after 1st OS
(D) Switch to Originator r-hFSH-alfa after 2nd OS
(E) Switch to Biosimilars after 2nd OS
(F) Switch to Originator r-hFSH-alfa after 1st OS
(G) Switch to Biosimilars after 3rd OS
(H) Originator r-hFSH-alfa only

Figure 3. Cost-effectiveness plane (German scenario analyses) CE plane with results for Germany only



Abbreviations: ART, assisted reproductive technology; CLBR, cumulative live birth rates; ICER, incremental cost-effectiveness ratio; LB, live birth; OS, ovarian stimulation; RWE, real world evidence; r-hFSH-alfa, recombinant human follicle-stimulating hormone

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