Cost-effectiveness Analysis of Reference Recombinant Human Follicle-stimulating Hormone Alfa (r-hFSH-alfa) and Urinary Highly **Purified Menopausal Gonadotropin (hMG-HP) Based on Data From A Large German Registry**

Klaus Bühler^{1,2}, Claudia Roeder³, Juan-Enrique Schwarze⁴, Monica Lispi^{4,5}, Arthur Allignol^{4*}, Thomas D'Hooghe^{4,6,7}, Edel Falla⁸, Vasily Lukyanov⁹, Robert Fischer¹⁰

¹Scientific Clinical Centre for Endometriosis, University Hospitals of Saarland, Saarbrücken, Germany; ²Department of Gynaecology, Jena-University Hospital-Friedrich Schiller University, Jena, Germany; ³Pharma Value Consulting, Oberwil, Switzerland; ⁴Merck Healthcare KGaA, Darmstadt, Germany; ⁵School of Clinical and Experimental Medicine, Unit of Endocrinology, University of Modena and Reggio Emilia, Modena, Italy; Department of Development and Regeneration, Laboratory of Endometrium, Endometriosis & Reproductive Medicine, KU Leuven, Leuven, Belgium; ⁷Department of Obstetrics, Gynecology, and Reproductive Sciences, Yale University Medical School, New Haven, USA; ®IQVIA Real World Solutions, London, UK; ®IQVIA Real World Solutions, Amsterdam The Netherlands; 10Gynecological Endocrinology and Reproductive Medicine, Fertility Centre Hamburg, 20095 Hamburg, Germany



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CONCLUSIONS



Based on a large German registry, using real-world data, OS with r-hFSH-alfa was associated with lower costs per live birth compared with **hMG-HP**



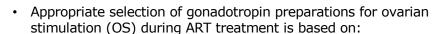
For up to three cumulative ART cycles, r-hFSH-alfa was found to be a cost-effective strategy compared with hMG-HP for ovarian stimulation



The robustness of the model data was confirmed in the sensitivity analyses



INTRODUCTION





Overall benefit-risk evaluation



Cost-effectiveness



Patient preference

- Cycles stimulated with reference follitropin alfa (r-hFSH-alfa, GONAL-f®, Merck Healthcare KGaA, Darmstadt, Germany) versus hMG-HP (Menogon® HP [Menopur®], Ferring Pharmaceuticals Ltd, Saint-Prex, Switzerland) had increased cumulative live birth rates and clinical and ongoing pregnancy rates in a large (>28,000 patients) real-world study¹
- To complement RWE, cost-effectiveness analyses can support informed decision making regarding the optimal gonadotropin to be used for OS based on a comparison of all costs associated with ART cycles
- Thus, to the best of our knowledge, this is the first cost-effectiveness analysis comparing cumulative live birth (including fresh and freezethaw embryo transfers) for r-hFSH-alfa with hMG-HP in Germany using real-world data to provide a more accurate reflection of clinical practice

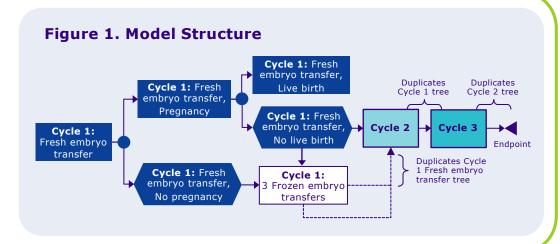


OBJECTIVES

To evaluate the real-world cumulative cost per live birth and cost-effectiveness of reference r-hFSH-alfa versus hMG-HP, for up to three cumulative ART cycles (maximum three stimulations and corresponding fresh and frozen embryo transfers)



- Retrospective RWE analysis of the costs per live birth for r-hFSH-alfa versus hMG-HP, based on data from a German IVF registry (RecDate), including 71 German IVF centres (January 2007-December 2010)³
- A decision-tree model was developed (Figure 1), using pregnancy and live birth states for up to three complete ART cycles (defined as all embryos transferred [fresh or frozen] after a single stimulation cycle)¹ with the same gonadotropin from RecDate as clinical inputs
- · Model outputs included total costs, live birth rates, costs per live birth, and ICER (difference in costs/difference in cumulative live birth between both treatments)
- Robustness of results to parameter input variation was assessed via sensitivity analyses





RESULTS

Table 1. Key Clinical and Cost-effectiveness Results (Cumulative)

	r-hFSH-alfa	hMG-HP	Difference
First complete ART cycle			
Live birth rate	25.3%	22.3%	3.0%
Cost per live birth	€17,938	€20,054	
ICER	€2,430		
Two complete ART cycles (cumulative)			
Live birth rate	30.9%	27.5%	3.5%
Cost per live birth	€18,251	€20,437	
ICER	€836		
Three complete ART cycles (cumulative)			
Live birth rate	31.9%	28.6%	3.4%
Cost per live birth	€18,473	€20,680	
ICER	Dominant		

- Treatment with r-hFSH-alfa resulted in higher adjusted cumulative live birth rates and lower costs per live birth versus hMG-HP (**Table 1**)
- Treatment with r-hFSH-alfa led to lower overall medication costs, as a lower dose was needed per live birth
- The ICER was €2,430 after the first ART cycle, €836 after the second ART cycle and becomes dominant after the third ART cycle (**Table 1**)
- The model results were most sensitive to the probability of live birth and pregnancy, compared with all clinical and cost inputs (Figure 2)
- The PSA for the third complete cumulative ART cycle shows that the majority of ICER data points were in the upper-right and lower-right quadrants of the cost-effectiveness plane, suggesting that results obtained from the analysis are robust and that treatment with r-hFSH-alfa can be considered cost-effective (Figure 3)

Figure 2. Tornado Diagram for OWSA for Live Birth

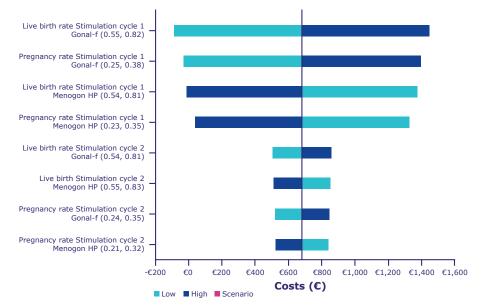
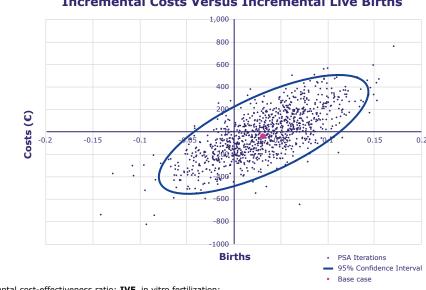


Figure 3. Cost-effectiveness Plane for the Third **Complete ART Cycle (PSA)**

Incremental Costs Versus Incremental Live Births



*Affiliation at the time of the analysis.

ART, assisted reproductive technologies; hMG-HP, highly purified human menopausal gonadotropin; ICER, incremental cost-effectiveness ratio; IVF, in vitro fertilizat OS, ovarian stimulation: OWSA, one-way sensitivity analysis: PSA, probabilistic sensitivity analysis r-hFSH-alfa, recombinant human follicle-stimulating hormone alfa: RWE, real-world evidence

DISCLOSURES: KFB has received honoraria are employees of Merck Healthcare KGaA, Darmstadt, Germany, Ferring, Bayer, Stiftung Endometriose Forschung, and TDH are employees of Merck Healthcare KGaA, Darmstadt, Germany. Am was an employee of Merck Healthcare KGaA, Darmstadt, Germany, Ferring, Bayer, Stiftung Endometriose Forschung, and TDH are employees of Merck Healthcare KGaA, Darmstadt, Germany. Am was an employee of Merck Healthcare KGaA, Darmstadt, Germany. Am was an employee of Merck Healthcare KGaA, Darmstadt, Germany. Am was an employee of IQVIA Real World Solutions, Amsterdam, NL. RF has received honoraria for lectures from Merck Healthcare KGaA, Darmstadt, Germany, and affiliates. ACKNOWLEDGEMENTS: Medical writing support was provided by Amy Evans of inScience Communications, Springer Healthcare Ltd, UK, and was funded by Merck Healthcare KGaA, Darmstadt, Germany