

## **Late Breaking Abstracts: Antimicrobials**

### **Rezafungin (Once Weekly) versus Standard Antimicrobial Regimen for Antifungal Prophylaxis in Allogeneic Haematopoietic Stem Cell Transplantation: ReSPECT, a Multicentre, Randomized, Double-Blind, Phase 3 Study**

Thursday, October 22, 2026

10:54 AM - 11:06 AM East Coast USA Time

Location: 206

#### **Co-Author(s)**

[Johan A. Maertens, MD PhD](#)

UZ Leuven  
Leuven, Vlaams-Brabant, Belgium

[Drew Winston, MD](#)

UCLA Medical Center, University of California, Los Angeles, CA, USA  
Los Angeles, California, United States

#### **Presenting Author(s)**

[Shariq Haider, MD, FRCPC, FACP, CCST](#)

Juravinski Hospital and Cancer Center  
Hamilton, Ontario, Canada

#### **Co-Author(s)**

[Francisco Javier López-Jiménez, MD, PhD](#)

Hospital Universitario Ramon y Cajal, IRYCIS, University of Alcalá Henares, Madrid, Spain  
Madrid, Madrid, Spain

[Matthias Breugelmans, Pharm D, PhD](#)

Mundipharma Research Ltd, Cambridge, UK  
Cambridge, England, United Kingdom

[Hosnieh Fathi, MD, FFPM](#)

Mundipharma Research Ltd, Cambridge, UK  
Cambridge, England, United Kingdom

**Yuri Martina, MD, PhD**

Mundipharma Research Ltd, Cambridge, UK  
Cambridge, England, United Kingdom

**Federica Sorá, MD, PhD**

University Cattolica del Sacro Cuore and Fondazione Policlinico Universitario Agostino  
Gemelli IRCCS, Rome, Italy  
Rome, Lazio, Italy

**Disclosure(s):**

**Shariq Haider, MD, FRCPC, FACP, CCST:** AVIR Pharmaecuticals: Grant/Research Support, Honoraria; Cidara Pharmaceuticals: Grant/Research Support; Merck: Advisor/Consultant

**Rezafungin (Once Weekly) versus Standard Antimicrobial Regimen for Antifungal Prophylaxis in Allogeneic Haematopoietic Stem Cell Transplantation: ReSPECT, a Multicentre, Randomized, Double-Blind, Phase 3 Study**

**Background:** Rezafungin (RZF) is a next-generation echinocandin with broad antifungal activity, including *Candida* spp., *Aspergillus* spp., and *Pneumocystis jirovecii* (PJ), and a differentiated PK/PD profile enabling once-weekly (QW) IV dosing. Rezafungin has the potential to offer a better tolerated option with simpler dosing to prevent invasive fungal disease (IFD) after allogeneic haematopoietic stem cell transplantation (allo-HSCT) compared with current daily (QD) standard antimicrobial regimens (SAR) used for antifungal prophylaxis.

**Methods:** ReSPECT is a Phase 3, multicentre, double-blind, randomized study that investigated single-agent RZF QW vs QD SAR to prevent IFD after allo-HSCT to Week 13. Eligible adults were randomized 2:1 to RZF IV infusion QW (400 mg loading dose on Day 1, 200 mg on subsequent weeks) or SAR. SAR comprised QD oral azole (fluconazole [FLZ] 400 mg QD or posaconazole [PCZ]; Day 1 300 mg BID, then 300 mg QD) plus trimethoprim/sulfamethoxazole (TMP/SMX) 80 mg/400 mg QD post engraftment. RZF or azole was initiated after cell infusion for 13 weeks. The primary endpoint was non-inferiority of rezafungin vs SAR for fungal-free survival (FFS; Table 1) on Day 90 (±7 days) post HSCT.

**Results:** Overall, 402 patients were randomized to RZF and 200 patients to SAR (FLZ n=172, PCZ n=25 [n=3 did not receive SAR]); a permanent switch from FLZ to PCZ was permitted for clinically significant acute graft vs host disease (n=20). Baseline characteristics were similar across the cohorts.

RZF was non-inferior to SAR for Day 90 FFS ( $P=0.0002$ ; Table 2). FFS failure due to IFD was infrequent across the cohorts (3.5% vs 4.5%; Table 2). IFI incidence due to key fungal species was also similar with RZF and SAR (Table 2).

While treatment-emergent adverse event (TEAE) incidence was similar (99.7% vs 100%), a smaller proportion of TEAEs led to dose reduction, interruption, or withdrawal of study drug in the RZF vs SAR cohorts (31.0% vs 47.7%).

**Conclusion:** For IFD prophylaxis (Day 90 FFS), RZF (IV, QW) was non-inferior to SAR (azole plus TMP/SMX, oral, QD) in adults undergoing allo-HSCT. RZF safety profile was consistent with its licensed indication for invasive candidiasis. This supports RZF as a convenient QW, non-oral option for antifungal prophylaxis in adult allo-HSCT recipients.

**Table 1. ReSPECT primary endpoint: Rezafungin QW vs SAR QD**

|                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Fungal-free survival at Day 90</b><br>(±7 days) <b>post HSCT:</b><br>Composite endpoint                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Survival, <i>and</i></li><li>• No proven or probable IFD (assessed by independent DRC, per modified 2020 EORTC-MSGERC) criteria), <i>and</i></li><li>• No non-study drug systemic antifungal therapy for &gt; 10 days (cumulative)</li></ul> |
| Statistical analysis                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"><li>• Non-inferiority: 95% CI lower limit of treatment difference (rezafungin minus SAR) &gt; -12.5%</li></ul>                                                                                                                                     |
| CI, confidence interval; DRC, data review committee; EORTC-MSGERC, European Organization for Research and Treatment of Cancer Mycoses Study Group Education and Research Consortium; IFD, invasive fungal disease; QD, once daily; QW, once weekly; SAR, standard antimicrobial regimen |                                                                                                                                                                                                                                                                                      |

**Table 2: Overview of ReSPECT primary endpoint (Intent-to-treat population)**

|                                                                                                                                                                                  | Rezafungin<br>(N=402)                             | SAR<br>(N=200) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|----------------|
| FFS (Day 90 [±7 days])                                                                                                                                                           | 60.7%                                             | 59.0%          |
|                                                                                                                                                                                  | Difference 1.6% (95% CI -6.2, 9.3) <sup>a,b</sup> |                |
|                                                                                                                                                                                  | P value: <i>P</i> =0.0002                         |                |
| FFS (Day 90 [±7 days]) failure                                                                                                                                                   |                                                   |                |
| No FFS (Day 90)                                                                                                                                                                  | 39.3%                                             | 41.0%          |
| Death                                                                                                                                                                            | 4.5%                                              | 5.5%           |
| Proven/probable IFD                                                                                                                                                              | 3.5%                                              | 4.5%           |
| Non-study systemic antifungal drugs for > 10 days (cumulative)                                                                                                                   | 27.4%                                             | 32.0%          |
| Indeterminate                                                                                                                                                                    | 10.0%                                             | 6.0%           |
|                                                                                                                                                                                  |                                                   |                |
| Proven/probable IFD species                                                                                                                                                      |                                                   |                |
| <i>Candida</i>                                                                                                                                                                   | 1.2%                                              | 1.0%           |
| <i>Aspergillus</i>                                                                                                                                                               | 2.0%                                              | 3.0%           |
| <i>Pneumocystis jirovecii</i>                                                                                                                                                    | 0.2%                                              | 0              |
| Other yeast or mould                                                                                                                                                             | 0.2%                                              | 0.5%           |
| <sup>a</sup> CI adjusted for randomization stratification factors: underlying disease, donor source (mismatched related/unrelated or haploidentical vs matched), and initial SAR |                                                   |                |
| <sup>b</sup> Non-inferiority margin for rezafungin minus SAR was achieved: 95% CI lower limit for the treatment difference was greater than -12.5%                               |                                                   |                |
| FFS, fungal-free survival; IFD, invasive fungal disease; SAR, standard antimicrobial regimen                                                                                     |                                                   |                |