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Safety and tolerability of Favipiravir compared to Ribavirin for the treatment of Lassa fever: A randomized controlled open-label phase II clinical trial

Cyril Erameh[1,2], Kevin Okwaraeke[3], Meike Pahlmann[4,5], Christine Kleist[6], Femi Babatunde[1], Ndapewa Ithete[4,5], Osahogie Edeawe[1], Cédric Mbavu[7], Julia Hinzmann[4,5], Veronika Schlicker[7], Francisca Sarpong[7], Camille Fritzell[8,9,10], Alexandre Duvignaud[8,9,11], Denis Malvy[8,9,11],Joseph Okoeguale[1,12], Reuben Eifediyi[1,12], Sylvanus Okogbenin[1,12], Marie Jaspard[8,9,10], Sebastian Wicha[6], Stephan Günther[4], Peter Akhideno[1,2], Oluwafemi Ayodeji[3], Michael Ramharter[7,5], Mirjam Groger[7,5]

[1]Institute of Lassa Fever Research and Control, Irrua Specialist Teaching Hospital, Irrua, Nigeria, [2]Department of Medicine, Irrua Specialist Teaching Hospital, Irrua, Nigeria, [3]Infection Control and Research Centre, Federal Medical Centre Owo, Michael Adekun Ajasin Road, PMB 1053, Owo, Ondo State, Nigeria, [4]Department of Virology, Bernhard Nocht Institute for Tropical Medicine (BNITM), Hamburg, Germany, [5]German Center for Infection Research (DZIF), Hamburg-Lübeck-Borstel-Riems, Hamburg, Germany, [6]Department of Clinical Pharmacy, Institute of Pharmacy, University of Hamburg, Hamburg, Germany, [7]Department of Tropical Medicine, Bernhard Nocht Institute for Tropical Medicine & I. Department of Medicine University Medical Center Hamburg-Eppendorf, Hamburg, Germany, [8]Univ. Bordeaux, Inserm 1219, IRD 271, Bordeaux Population Health, 146 Rue Léo Saignat, F-33076 Bordeaux, France, [9]Programme PAC-CI/ANRS Research Site, CHU de Treichville, 18 BP 1954, Abidjan 18, Côte d'Ivoire, [10]The Alliance for International Medical Action, Route de l'Aéroport, Rue NG 96, BP 15530, Dakar, Senegal, [11]Department of Infectious Diseases and Tropical Medicine, Division of Tropical Medicine and Clinical International Health, CHU de Bordeaux, Hôpital Pellegrin, Place Amélie Raba Léon, F-33076 Bordeaux, France, [12]Department of Obstetrics and Gynecology, Irrua Specialist Teaching Hospital, Irrua, Nigeria

[&]Corresponding author: Cyril Erameh, Institute of Lassa Fever Research and Control, Irrua Specialist Teaching Hospital, Irrua, Nigeria **Email:** cyrilerameh@gmail.com

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Introduction

The Lassa virus (LV) causes Lassa fever (LF), a severe re-emerging disease. It affects several West African nations, with Nigeria having the greatest case burden. Currently, only supportive care and ribavirin are available for treatment. There is, however, little evidence on the efficacy of ribavirin in LF. Recent research found that *in vivo* plasma concentrations are likely insufficient for antiviral effects. Thus, new LF medicines are urgently required. Favipiravir, a broad-spectrum antiviral for pandemic influenza, has also being tested for other viruses. It is effective against LV in pre-clinical trials. The aim of this clinical trial was to evaluate the safety, tolerability and pharmacokinetics of repurposed favipiravir for LF.

Methods

LF patients (hospitalized and PCR confirmed) were recruited to this randomized controlled open-label phase II clinical trial in Nigeria's Irrua Specialist Teaching Hospital and Federal Medical Centre Owo, the world's biggest LF treatment centres. Patients were randomized in a 1:1

ratio to I.V ribavirin and oral favipiravir. Clinical assessments including ECG, and blood sampling for pharmacokinetics (PK) as well as virological, serological, immunological, haematological, biochemistry analyses were done during screening and thereafter until day 10.

Results

Between August 2021 and October 2022, 41 LF patients were randomized in the study. 36 participants completed follow-up. Treatment Emergent Adverse Events occurred on 16/20 (80%) on favipiravir and 14/21 (66.7%) on ribavirin and were similarly distributed between treatment arms. No severe or serious adverse events were observed under favipiravir. One life-threatening event occurred with ribavirin. PK analysis of favipiravir showed reliable exposure with maximum plasma concentration of 50.9 mg/L in steady state, half-life of 10.9 hours, and $AUC_{(0\text{-}240h)}$ of 9275mg/L*h.

Conclusion

These first clinical trial data on the safety, tolerability and pharmacokinetics of favipiravir as a treatment candidate for LF indicate good safety and tolerability. Further investigation into larger trials is underway.