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Fagaricine, a new immunorestorative phytomedicine from *Zanthoxylum heitzii*: Preclinical and multicenter cohort clinical studies based on HIV-infected patients in six countries

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Abstract

The present investigation was carried out to evaluate the safety of Fagaricine, an aqueous extract of *Zanthoxylum heitzii* by determining its potential toxicity after acute and subchronic oral administration in rodents, and his clinical benefits on HIV-infected patients. For the acute study, Fagaricine was administered to mice in orally single doses of 0-10 g/kg. General behaviour adverse effects and mortality were determined for 7 days. In the subchronic dose study, the extract was administered at doses of 0-1275 mg/kg daily for 35 days. Biochemical and haematological parameters were determined at the end of 35 days of daily administration. For the clinical benefits of Fagaricine, multicentre cohort observations were realised in six countries, on 75 patients. All patients received two tablets of the fixed-dose containing 100 mg of Fagaricine twice daily for 24 weeks. Clinical benefits were evaluated over active control on CD4 counts. In the In the acute study in mice, no adverse effects and mortality was observed. In the subchronic study, variations were observed with biological, heamatologic-

