

Discovery, Development, Article PHARMACEUTICALS Inventions and Patent Review of Fexinidazole: The First All-Oral Therapy for Human African Trypanosomiasis

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Abstract: Human African trypanosomiasis (HAT or 'sleeping sickness') is a neglected tropical disease. If untreated, it is always fatal and leads to death. A few treatments are available for HAT, but most of them require a skilled professional, which increases the financial burden on the patient. Recently, fexinidazole (FEX) has been approved by the European Medicine Agency (EMA) and the United States Food and Drug Administration (USFDA) as the first all-oral therapy for the treatment of stage-1 (hemolymphatic) as well as stage-2 (meningoencephalitic) of HAT. Before the FEX approval, there were separate treatments for stage-1 and stage-2 of HAT. This study reviews the discovery, development timeline, inventions, and patent literature of FEX. It was first approved by EMA and USFDA in 2018 and 2021, respectively. FEX was also added to the World Health Organization's list of essential drugs in 2019. The patent literature search revealed many types of patents/patent applications (compound, salt, process, method of treatment, drug combinations, and compositions) related to FEX, which have been summarized in this article. The authors foresee a great scope to develop more inventions based on FEX (novel salts, polymorphs, drug conjugates, cyclodextrin complex, etc.) for the treatment of many protozoal diseases (Leishmaniasis and Chagas disease), inflammatory diseases, and other microbial infections. New combinations of FEX with other treatments of HAT may also provide fruitful results. This review might be useful to the scientists working on the HAT and other neglected diseases to develop novel inventions and innovations of therapeutic relevance.