

Suramin IV



Ongoing Phase 3 for Human African trypanosomiasis (HAT), qualifying for an FDA Priority Review Voucher (PRV) in neglected tropical diseases (NCE)

MAVERICK
Financial Opportunity

ABOUT

Suramin IV is being developed for Human African Trypanosomiasis (HAT). Because HAT is included on the FDA's list of tropical diseases eligible for a Priority Review Voucher, approval in this indication could potentially qualify the program for a Priority Review Voucher, subject to applicable FDA requirements. The HAT program may also serve as a strategic bridge toward Autism Spectrum Disorder (ASD) as a potential follow-on indication.

STAGE

Suramin IV for HAT is currently in Phase 3 development. A Phase 2 study on ASD has been completed.

INDICATION

Suramin IV is being developed for the treatment of *Trypanosoma brucei rhodesiense*, the acute and rapidly progressing form of Human African Trypanosomiasis. HAT is a neglected tropical disease, and this specific disease is included on the FDA list of tropical diseases for which a Priority Review Voucher (PRV) may be granted. Following HAT, ASD could be pursued as an additional indication.

BENEFIT

Suramin IV is a standardized intravenous formulation of the long-established standard of care for rhodesiense HAT. Although suramin has been used globally for decades and is recognized by the WHO and CDC, it has never been FDA-approved for any indication in the U.S. By formalizing the regulatory path for this life-saving therapy, the program aims to become the first FDA-approved suramin product in the U.S. while also creating a PRV opportunity.

IP RIGHTS / EXCLUSIVITY

**FDA Orphan Drug Designation
HAT indication**

Forward-Looking Statements



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