

U.S. FDA approves chemo group's benznidazole to treat children with Chagas disease

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Singapore – The U.S. Food and Drug Administration (FDA) approved Chemo Research's New Drug Application (NDA) for benznidazole. This is the first drug ever approved by the FDA to treat Chagas disease.

Benznidazole is an essential medicine for Chagas disease, a dangerous parasitic disease that affects an estimated 6 to 8 million people worldwide. In the United States, an estimated 300,000 people are living with Chagas disease. Previously, it was available through the Centers for Disease Control and Prevention, but was not FDA approved.

"The approval of benznidazole represents a major milestone in the US and global response to address Chagas disease," said Nick Haggard, CEO of Chemo Group. "We are excited to have the opportunity to fulfil this medical need and make a meaningful difference in the lives of Chagas patients. The FDA's decision approves benznidazole for children ages 2-12 years old. We look forward to continuing our strong collaboration with the FDA to expand indication."

Chemo Group played a central role in registering benznidazole with the FDA, in close collaboration with its US-based pharmaceutical division Exeltis, corporate social responsibility partner Mundo Sano, with the support of the Drugs for Neglected Diseases initiative (DNDi), a non-profit drug development organization. DNDi supported U.S. registration through provision of technical expertise and sharing of data from DNDi-led clinical trials. The approval of benznidazole will facilitate the delivery of life-saving medical treatment to people with Chagas disease.