

For the treatment of chorea associated with Huntington's disease

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Familial Adenomatous Polyposis Treatment Gets FDA Fast Track Status

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The U.S. Food and Drug Administration (FDA) granted "Fast-Track" status to CPP-1X/sul for the treatment of adults with familial adenomatous polyposis (FAP) this morning.

CPP-1x/sup is being developed by Cancer Prevention Pharmaceuticals and Sucampo Pharmaceuticals.

CPP-1x is an ornithine decarboxylase (ODC) inhibitor, while sulindac is a non-steroidal anti-inflammatory drug (NSAID). The combination drug is currently in a Phase 3 clinical trial, and would be the first effective treatment for the rare disease. The designation is intended to accelerate development and advance the review of drugs that treat severe conditions and occupy an unmet need.

FAP is a genetic condition in which several adenomatous polyps develop in the large intestine and rectum. Patients with FAP typically begin to experience the growth of several benign polyps in the colon as early as their teenage years which, unless removed, will eventually become malignant. Per the NIH, the average age at which an individual develops colon cancer in classic FAP is 39 years.

FAP has an orphan drug designation in both the U.S. and Europe, with a prevalence of about 1 in 10,000, and approximately 30,000 cases currently in the United States.

"The FDA's decision to grant Fast Track status for CPP-1X/sul is good news for FAP patients who currently have no approved therapies," said Jeff Jacob, CPP's Chair and CEO in a press release.

"It also means a potentially streamlined path to commercialization for CPP. The continuing support of our expert partner Sucampo Pharmaceuticals, Inc. in the U.S. should help advance our FAP-310 clinical trial to completion and bring to market a first-in-class pharmaco-prevention therapeutic in FAP."



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The aforementioned Phase 3 clinical trial (FAP-310) is intended to evaluate the safety and efficacy of eflornithine plus sulindac, and determine if the combination is superior to eflornithine or sulindac as single agents. It includes the study of clinically important events, including disease progression and survival rate.

The primary outcome measure of the trial is delaying time to the first occurrence of any FAP-related event, and secondary outcome measures include the presence or absence of an ODC polymorphism and the excretion of 4 urinary polyamines up to 48 months from the initial treatment.

Other outcome measures include pharmacokinetics of the drug, analysis of adverse events (AEs), and patient-reported quality of life, among others.

In January of last year, CPP received \$8 million from Sucampo Pharmaceuticals, Inc. in exchange for the exclusive licensing rights for commercializing the drug in North America.

For more updates from the FDA, including applications, designations and approvals, follow *Rare Disease Report* on Facebook and Twitter.



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