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Devimistat:

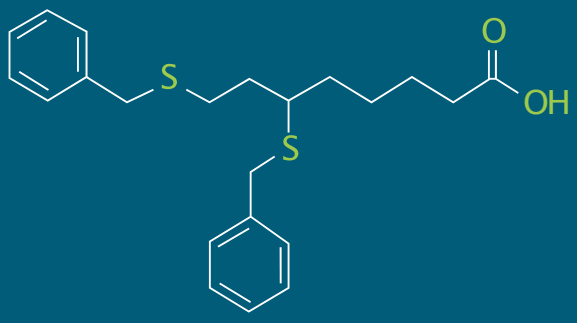
A First-in-Class Therapeutic Agent Targeting Cancer Cell Metabolism

What is devimistat?

- Devimistat is a **first-in-class investigational small-molecule** (lipoate analog)
- In **nonclinical studies** (including GLP Tox studies), devimistat has **exhibited excellent safety and anticancer activity**
- Devimistat was clinically investigated in multiple hematological malignancies and solid tumors and exhibited a very **good signal of efficacy**
- Devimistat was granted **'Orphan Drug Designation'** by the U.S. FDA for biliary tract cancer, Burkitt's lymphoma, soft tissue sarcoma, myelodysplastic syndrome (MDS), and peripheral T-cell lymphoma. Devimistat was granted 'Orphan Drug Designation' by EMA for biliary tract cancer and Burkitt's lymphoma.
- Devimistat has IP **protection until 2028 and potentially beyond** across U.S., Canada, EU, Israel, Australia, and major markets of Asia (China, Hong Kong, Japan, South Korea, Taiwan)

Devimistat: Clinical Trials

- **21** ongoing or completed **clinical trials** to date. Four ongoing trials in solid tumors and hematological malignancies.
- Over **890 patients** have received one or more doses of devimistat. It was well tolerated and demonstrated a very good signal **of efficacy with excellent response** rate and **survival statistics** in several tumor types.
- **Initiated phase 2 study** of devimistat in combination with gemcitabine and cisplatin in patients with **biliary tract cancer**
- **Initiated a phase 1/2 trial** of devimistat, in combination with hydroxychloroquine in patients with relapsed or refractory **clear cell sarcoma**
- **Expanded the phase 2 study** of devimistat monotherapy in patients with relapsed or refractory **Burkitt's lymphoma**
- In a phase IB study in patients with advanced unresectable **biliary tract cancer,** devimistat in combination with gemcitabine and cisplatin exhibited **45% objective response rate (ORR) with a median progression-free survival (PFS) of 14.9 months**



Devimistat: Mechanism of Action

- CPI-613® (devimistat) is an analog of normally transient, acylated catalytic intermediates of the enzyme cofactor lipoate
- CPI-613® (devimistat) tumor selectivity is enhanced by tumor-drug retention
- CPI-613® (devimistat) turns off the mitochondrial tricarboxylic acid (TCA) cycle
- in cancer cells
- CPI-613® (devimistat) induces mitochondrial stress by activating a redox feedback loop
- CPI-613® (devimistat) induces metabolic stress leading to apoptotic and necrotic cancer