ORAL PACLITAXEL + ENCEQUIDAR

ONCOLOGY
MULTIPLE INDICATIONS

Athenex

DISEASE BURDEN

Cancer is the second leading cause of death worldwide, and 10 million deaths in 2020 were attributed to cancer. Low-and-middle-income countries (LMICs) shoulder most of the cancer burden.

CLINICAL RELEVANCE

Paclitaxel is part of the taxane class which is used in oncology treatments for a variety of cancers, including breast, lung, prostate, stomach and ovarian cancers, among others and is an integral part of the standard of care. An oral formulation of paclitaxel, enabled by encequidar, a novel P-glycoprotein pump inhibitor, is attractive due to its ease of administration, which could include the option for patients to take it at home without requiring intravenous access.

INTELLECTUAL PROPERTY LANDSCAPE

While paclitaxel is off patent and encequidar primary patent is to expire in early 2024, Hanmi owns patents on paclitaxel oral formulation as well as on the combination that have been filed or granted in many LMICS with an expected expiry in 2036. Additional secondary patents on encequidar have been filed in many LMICs and are expected to expire between 2031 and 2033.

SERVICE DELIVERY ENABLERS

Service delivery enablers change according to the type of cancer assessed. In general, capacity of cancer diagnosis is slowly improving in LMICs. Oral therapies represent an opportunity to facilitate the delivery of treatment.

REGULATORY

Oral paclitaxel has not yet been approved by any regulatory authority and there is insufficient data to determine bioequivalence studies requirements or the likelihood of a biowaiver.

MANUFACTURING

Limited data available to assess the manufacturing complexity of oral paclitaxel.

MARKET

This medicine is still in the R&D pipeline and therefore little is known about its potential positioning in treatment protocols, pricing, and overall access plans