

Lantern Pharma: precision medicine pioneers

A Dallas-based biotech company is leading a wave of innovation in cancer treatment that is being tailored to the cancer patients who are most likely to respond.

According to a recent study, the overall success rate for drugs moving through clinical trials to approval by the US Food and Drug Administration is only about 10%. Even though cancer is the most closely studied disease for drug development, oncology drugs have the toughest time making their way to the clinic. One major reason for such failure is the heterogeneity of cancers, which leads to multidrug resistance and the inability of one drug to treat all patients. Many valuable drugs that work for a subset of patients are shelved because they don't work in many patients, and there is an inability to identify the right drugs for the right patients.

To address this problem, Lantern Pharma is reinventing the cancer drug development process by tailoring multiple promising precision drug programs to the right cancer patients by using advanced genomics and artificial intelligence (AI). The company has in-licensed, validated, and de-risked clinical-stage drugs that are discontinued for development. Lantern identifies biomarkers for patient response for each drug and further validates them by conducting small, focused phase 2 clinical trials to greatly increase their value, thereby creating multiple exit points for each drug.

Rather than discovering drugs from scratch, Lantern identifies, partners with other companies on, licenses, or acquires abandoned late-stage clinical drugs that are effective in only some patients. Using advanced genomics, data analytics, and AI, the company 'rescues' these valuable drugs and repurposes them by using molecular profiling to identify the specific patients who respond favorably to treatment. Responding patients are screened for a response biomarker, stratified, and treated in a narrow scope of clinical trials. The drug, along with the newly identified biomarker diagnostic for drug response, can then be partnered on with or licensed to a pharma partner. This process of targeting certain genomic profiles creates truly precise therapies and addresses a significant unmet need in the cancer market.

"Lantern Pharma stands as one of the emerging global leaders in anticancer precision medicine," said Arun Asaithambi, the company's cofounder. "Ultimately, our approach will bring a broader selection of promising anticancer drugs to market, increase the success rate of the clinical development process and improve outcomes for patients who do not respond to currently available drugs."

Made-to-measure treatments

Lantern Pharma's precision medicine approach consists of five broad modules referred to collectively as the 5M.AI Biomarker Approach (Fig. 1). First, patient data from clinical trials are analyzed to determine drug responses, clinical efficacy, and safety. The second

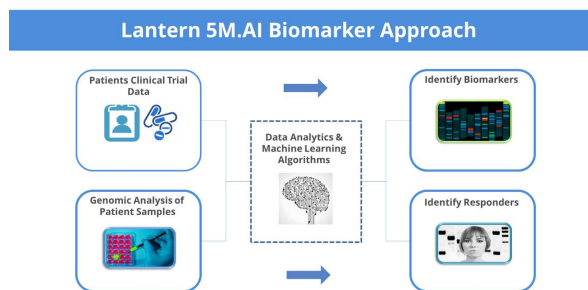


Figure 1: Lantern Pharma's precision medicine approach. The 5M.AI Biomarker Approach consists of five broad modules. Firstly patient data from clinical trials are analyzed. Lab genomic analysis of patient samples and genetic models are then performed. Data analytics and the AI stage predict meaningful biomarkers and responders at the third stage. Finally predictive biomarkers and of the subgroup of responders that express the predictive biomarkers are identified.

stage consists of lab genomic analysis of patient samples and genetic models. In the data analytics and AI stage, algorithms analyze and query public reference databases to predict meaningful biomarkers and responders. The last two stages involve the identification of predictive biomarkers and of the subgroup of responders that express the predictive biomarkers.

A key component of the 5M.AI approach is a proprietary machine learning algorithm called Rescue Algorithm for Drug Repurposing (RADR), which identifies abandoned clinical trial drugs that could be rescued and repurposed. The algorithm analyzes patient clinical trial data consisting of drug efficacy, toxicity, mechanism of action, and comparisons with disease signatures and approved drug signatures from reference data sets to predict drugs that could have the potential to be used in certain patients.

Currently, Lantern's pipeline consists of three drugs: Tavocept (LP-300), Irofulven-1 (LP-100), and Irofulven-2 (LP-184). Tavocept, which was in-licensed from BioNumerik Pharmaceuticals last year, is a multi-targeted agent that has undergone phase 1/2 trials in more than 600 patients with non-small-cell lung cancer. Lantern is currently analyzing drug responses and expects to out-license the agent later this year.

Irofulvens are a class of antitumor agents that show promise for overcoming multidrug resistance, a major factor contributing to the failure of chemotherapeutic agents. Irofulven-1 is an inhibitor of RNA polymerase II that has undergone more than 38 phase 1/2 trials in more than 1,300 patients with hormone-refractory prostate cancer. This drug was in-licensed from AFC LLC in 2014 and out-licensed to a European company in 2015.

Meanwhile, Irofulven-2 is a next-generation agent that offers a tenfold increase in efficacy, less toxicity, and an improved pharmacokinetic profile compared to Irofulven-1, including a longer half-life. Irofulven-2,

which was also in-licensed from AFC LLC in 2014, is currently undergoing preclinical trials for ovarian cancer and is expected to be out-licensed.

Goals for the future

Lantern has identified more than 50 other drugs that would be good candidates for the 5M.AI approach. The company's goal is to develop more than five precision oncology treatments in the next two years. One important area of focus will be the effectiveness of abandoned targeted agents that can be combined with immuno-oncology drugs to produce a synergistic therapeutic effect, which could improve survival rates for people with lung cancer, melanoma, and other solid tumors.

Moving forward, the company will continue to partner with drug companies to advance promising personalized medicine programs for cancer patients. "Within the next six years, the precision medicine market is expected to reach nearly \$88 billion and has the potential to impact all cancer patients. Drug rescue and repurposing in oncology is a high-growth segment and expected to contribute to as much as 25 to 30 percent of new therapeutic approvals and significantly reduce development costs," Asaithambi said. "We foresee our investments and partnerships in such an approach as a viable strategy to alleviate the healthcare burden and mark the beginning of a healthcare revolution."

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