Lantern Pharma
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Lantern Pharma
Pioneering Precision Medicine

Pioneering precision medicine by tailoring the right drugs to the right cancer patients

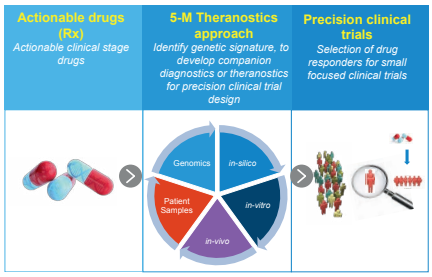
New biotech company Lantern Pharma is leading a wave of innovation in cancer treatment by bringing the best therapies to the patients who are most likely to respond.

According to a recent study[1], the overall success rate for drugs moving through clinical trials to US Food and Drug Administration (FDA) approval is only about 10%, and on average the full approval process takes 14 years and more than a billion dollars to be completed. Even though cancer therapy is the most active area of study in drug development, oncology drugs have the toughest time making their way through to the clinic. One major reason for their failure is the heterogeneity of cancers. Every patient, every cancer, and even the cells within certain types of tumors can be different, leading to multi-drug resistance and the inability of one drug to treat all patients with a given disease. Many valuable drugs that work in a subset of patients are shelved because they do not work in many other patients or because researchers are unable to identify the right patients for a particular treatment.

To address this problem, Lantern Pharma is re-inventing the cancer-drug-development process by combining clinical-stage drugs with next-generation companion diagnostics or theranostics that can predict which patients will benefit the most from its drugs. By incorporating biomarker-based genetic screening as early as phase 1/2, the company is taking a companion-diagnostic codevelopment approach that holds great promise for increasing response rates, especially for multi-drug-resistant cancers, enhancing confidence in patient selection, streamlining the clinical trial process, and reducing the time and cost required for drug development and commercialization.

> **"Lantern Pharma stands as one of the emerging global leaders in anticancer precision medicine"**
>
> Arun Asaithambi, cofounder

The first class of drugs in the Lantern pipeline comprises the irofulvens. This new class of antitumor agents shows promise for overcoming multi-drug resistance—a major factor contributing to the failure of chemotherapeutic agents. Lantern will continue to advance this unique class of drugs against hard-to-treat multi-drug-resistant cancers. The company's strategy is to conduct focused clinical trials combining irofulvens with biomarker-based companion diagnostic tests that prospectively identify subjects likely to respond to the drugs. Currently, genetic screening of likely responders is being conducted with a partner.



Lantern Pharma's precision approach.

"Precision medicine is revolutionizing health care by combining cancer therapeutics with selective diagnostic tests and personalizing patient treatment," said Arun Asaithambi, the company's cofounder, executive lead, and director of operations. "Lantern Pharma stands as one of the emerging global leaders in anticancer precision medicine. 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."

Tailoring treatments

Lantern Pharma's precision medicine approach consists of five broad modules, collectively referred to as the '5M approach'. First an *in silico* module that stratifies patients into responders and nonresponders is used. Multiple layers of population information, including drug-response and genomic data sets from early-phase clinical trials, are evaluated. In addition, candidate drugs are assessed in terms of their potency, efficacy, safety, breadth of indications, probable mechanism of action, target genes, and activity against multi-drug-resistant cancers. Potentially actionable genetic alterations correlating to a response to a particular drug are selected.

In the next stage, an *in vitro* module is used to identify potential biomarkers or genetic signatures. For example, a panel of carefully chosen cancer cell lines and matched normal controls are used with the drug of interest to generate dose-response curves based on prior *in silico* analysis. Cell lines are then simply classified as sensitive or resistant on the basis of the inhibitory concentration profile of the drug. Whole-exome sequencing or RNA-seq is performed on DNA or mRNA isolated from a subset of the cell lines considered extremely sensitive or resistant. This analysis reveals genetic abnormalities that serve as a foundation for the assembly of a biomarker panel, which can then be validated against primary tumor samples or compared with databanks for concordance analysis.

To develop promising biomarkers or genetic signatures, the company uses an *in vivo* module in which tumorigenic sensitive cells with an adequately defined genetic background are injected into animals to recapitulate a physiological tumor model. Tests are performed with the drug of interest, and responses are monitored to gain further support for developing the biomarkers previously discovered. Patient-derived xenografts are then used in a subsequent critical confirmatory approach. This leads to a better model for predicting drug responses in an actual, focused clinical trial.

Lastly, the biopsy/companion diagnostics module is used to validate biomarkers or genetic signatures, stratify patients, and develop companion diagnostics. The power of genomics, especially next-generation sequencing of patient samples, is used to stratify patients according to their genetic code. In the drug-testing stage, the company identifies responders on this basis, and the resulting companion diagnostic tests are submitted for FDA approval.

Using its signature 5M approach, Lantern Pharma is developing specific diagnostics to identify likely responders for enrollment in focused phase 2 clinical trials for advanced solid tumors. Moving forward, the company's strategy will be to acquire or partner with promising drug and diagnostic companies to continue to advance promising personalized medicine programs for cancer patients.

"Given their crucial role in disease assessment and treatment, a theranostic-based precision drug development process will continue to advance patient stratification and future oncology clinical trials, enable the approval of new oncology drugs, and not only promote better patient outcomes but minimize adverse events," said Asaithambi. "We foresee our investments and partnerships in such an approach as a viable strategy to alleviate the health care burden and mark the beginning of a health care revolution."

1. Hay, M. *et al. Nature Biotechnology* **32**, 40–51 (2014).

contact
Arun Asaithambi, Executive Lead
Lantern Pharma
Dallas, Texas, USA
Tel: +1-515-231-2065
Email: arun@lanternpharma.com