BeyondSpring plans three-pronged attack on cancer

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The CEO of BeyondSpring said the company hopes to make its name with a new lung cancer drug and an innovative R&D strategy.

Dr Lan Huang is a biotech entrepreneur with a chemistry Ph. D., from the University of California at Berkeley, and says the company models suggest peak sales in excess of $1 billion.

BeyondSpring's R&D strategy is to cut costs and time by conducting around 80% of a global trial in China, interim results of a late-stage lung cancer trial are due in early 2018.

As previously reported by pharmaphorum, New York-based BeyondSpring has begun late-stage development of plinabulin in non-small cell lung cancer, using a business model utilising the company's links with regulators in China to expedite development.

Its lead candidate, plinabulin could also have another indication as a stimulator of white blood cell activity following chemotherapy – which could make for sales in excess of a billion dollars, according to Dr Lan Huang.

Speaking to pharmaphorum, Huang said the approach will allow clinical development in a fraction of the time – and the cost – of a typical cancer drug.

"This one will cost us around $20 million to do, in about two and half to three years. A global trial of this type could usually cost $100m over five years – so you can see that our model is very effective."

"People are more and more using China for clinical research for their global trials – for the simple reason that it has a huge population."

The list of drugs developed in this way includes Bayer's Nexavar (sorafenib), Pfizer's Xalkori (crizotinib), and Boehringer Ingelheim's Giotrif (afatinib).

This lean development process, plus the lower cost of producing a small molecule, translates into much better margin for shareholders, said Huang.

Plinabulin, a small molecule with lower production costs compared with large antibody-based medicines, could therefore be real moneyspinner if approved in lung cancer.

The drug's mechanism also gives it a potential use as a white blood cell booster following chemotherapy, which could compete on cost and clinical performance with existing granulocyte-stimulating colony factor medicines

Dr Huang was cagey about pricing but said the drug could be priced in line with GCSF biosimilars in the neutropenia indication – around 15% lower than the original, while maintaining a healthy margin thanks to the lower costs.

Dr Huang (pictured) said plinabulin works by encouraging tubulin depolymerisation in cancer cells – which generates an amplified immune response.

It also disrupts microtubules critical for cell division, leading to cancer cell death via the JNK pathway. The third prong of the attack is to destabilise tubulin in endothelial cells in the tumour, collapsing and blocking blood vessels feeding the tumour and inhibiting their growth.

Phase 2 data suggests medium overall survival of plinabulin in combination with docetaxel is 11.3 months, compared with 6.7 months with docetaxel.

By working along the JNK pathway, plinabulin also has a second use in mitigating chemotherapy-introduced neutropenia.

This different mechanism of action allows plinabulin to be taken alongside chemotherapy, unlike GCSF where treatment is delayed. Data so far suggest that side effects such as bone pain are less frequent, said Dr Huang.

Plinabulin is also in early stage development with Bristol-Myers Squibb's nivolumab in lung cancer.

Huang said the company is "open minded" about how to market the drug if approved, suggesting a licensing or partnering deal with a big pharma company is possible. Inside China, BeyondSpring will market plinabulin itself – a job made easy by the company's contacts and the country's centralised health system.

According to Dr Huang, the company's name refers to a desire to move beyond borders, and to move forward from the growing season into harvest time.

While the lung cancer market is undoubtedly tough, if Dr Huang is right, the company could reap the benefits if plinabulin lives up to expectations.

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