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Hutchison MediPharma's Solid Tumor Drug First Oncology Project To Enter SFDA Fast-track Approval

SHANGHAI - China's State FDA held a pre-IND meeting June 17 with Shanghai-based Hutchison MediPharma on its Phase I development plan for its solid tumor drug HMPL-012, the company told *PharmAsia News.*

The meeting represented the first such communication for an oncology project since SFDA established pre-IND meetings under its fast-track approval mechanism. Similar to U.S. FDA's pre-IND meetings, the communication mechanism encourages discussion of specific issues in advance to expedite approval.

"The pre-IND meeting with the Center for Drug Evaluation of the SFDA was extremely helpful for us," Hutchison MediPharma CEO Samantha Du said in an interview. "It gave us a great opportunity to exchange ideas with the agency about key drug development issues and helped us understand the SFDA's position. We are pleased to learn that the SFDA is very supportive of new drug development in China," Du noted.

She said regular communication with the agency can help speed up the IND approval process and accelerate new drug development in China. Future meetings can also be requested based on project needs.

SFDA issued its special approval procedure in January to accelerate approval for four categories of drugs: (1) active pharmaceutical ingredients new to the Chinese market; (2) drugs, APIs or biological products that have not been approved worldwide; (3) new treatments for AIDS, cancers and other rare diseases with significant efficacy over current treatments; and (4) new drugs targeting diseases without treatment.

Under the fast-track procedure, CDE has five days to decide whether to accept an application if the drug is eligible under the first and second categories. For drugs under the third and fourth categories, CDE can answer the application in 20 days (PharmAsia News, Jan. 12, 2009).

Since the procedure was issued, SFDA has granted fast-track approvals to H1N1 vaccines (PharmAsia News, June 10, 2009) and AIDS treatments (PharmAsia News, March 27, 2009).

The fast-track procedure shortens the IND approval period from 90 days to 80 days and the NDA timeline from 150 days to 120 days.

Last year, Hutchison froze development of cancer drug HMPL-002 after Phase II clinical trials in China failed to show efficacy in patients with non-small cell lung cancer. The company shifted its focus on developing other products in its pipeline including HMPL004 for autoimmune disease, HMPL-011 for inflammation, and oncology products HMPL-012 and HMPL-013 (PharmAsia News, Jan. 9, 2009).

Hutchison has partnered with a number of multinational companies. Johnson & Johnson announced in April during the opening ceremony of its R&D center in Shanghai that it chose Hutchison as its first partner in China. The two companies are cooperating in areas of inflammation and immunology (PharmAsia News, April 17, 2009).

Hutchison signed a second partnership agreement in December with Eli Lilly on drug discovery and development (PharmAsia News, Dec. 1, 2008). The company had formed an earlier partnership with Lilly in 2007 to identify lead drug candidates in inflammation and oncology (PharmAsia News, Aug. 21, 2007).

Hutchinson MediPharma and its parent company Chi-Med are also collaborating with Germany's Merck KGaA to discover novel small molecule oncologics sourced from traditional Chinese medicines ('The Pink Sheet' DAILY, Nov. 22, 2006).

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