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CEO Podcast: Hengrui's US Subsidiary's CEO, CMO On Chinese Pharma Going Global

Luzsana Execs Talk On Challenges And Opportunities

by Brian Yang

While many pharma firms in China choose to partner with US companies, Jiangsu Hengrui is relying on itself to go global. The Chinese pharma giant is betting on its newly established US subsidiary Luzsana in a major move to make its wide-ranging products more available, accessible and affordable to patients in the US and the rest of the world.

(*This is the second instalment in a new China Biotech CEO Podcast series, in which top executives sit down to discuss key issues impacting innovative drug development in China, potentially the largest pharma market in the world. The first episode was with CANbridge Pharmaceuticals Inc. CEO James Xue*: (Also see "*China Biotech CEO Podcast: CANbridge's Xue On Orphan Drug Coverage, Financing, Gene Therapy*" - Scrip, 27 Apr, 2022.))

Billed as "one of a kind" operation, major Chinese drug firm *Jiangsu Hengrui Medicine Co., Ltd.* has set up a US subsidiary, Luzsana Biotechnology, from which two top executives sat down with *Scrip* for an in-depth audio interview. CEO Scott Filosi previously served as chief commercial officer at *Merck KGaA* and chief medical officer Joseph Eid successfully led clinical development and medical affairs departments at *Roche Holding AG*, *Merck & Co., Inc.* and *Bristol Myers Squibb Company*.

Armed with 11 assets selected from Jiangsu Hengrui in its pipeline, the start-up has already had a good start. Its development portfolio includes several oncology drugs in late-stage development including the PD-1 checkpoint inhibitor AiRuiKa (camrelizumab), being developed in combination with the VEGFR inhibitor rivoceranib for hepatocellular carcinoma, the PARP inhibitor AiRuiYi (fuzuloparib) for prostate cancer, and SHR-3680, AR inhibitor for high-risk

prostate cancer.

Aiming to expand Luzsana's capabilities and to co-develop the assets with Jiangsu Hengrui, the executives describe the US operation as “both the child and the partner” to the Shanghai-listed drug maker.

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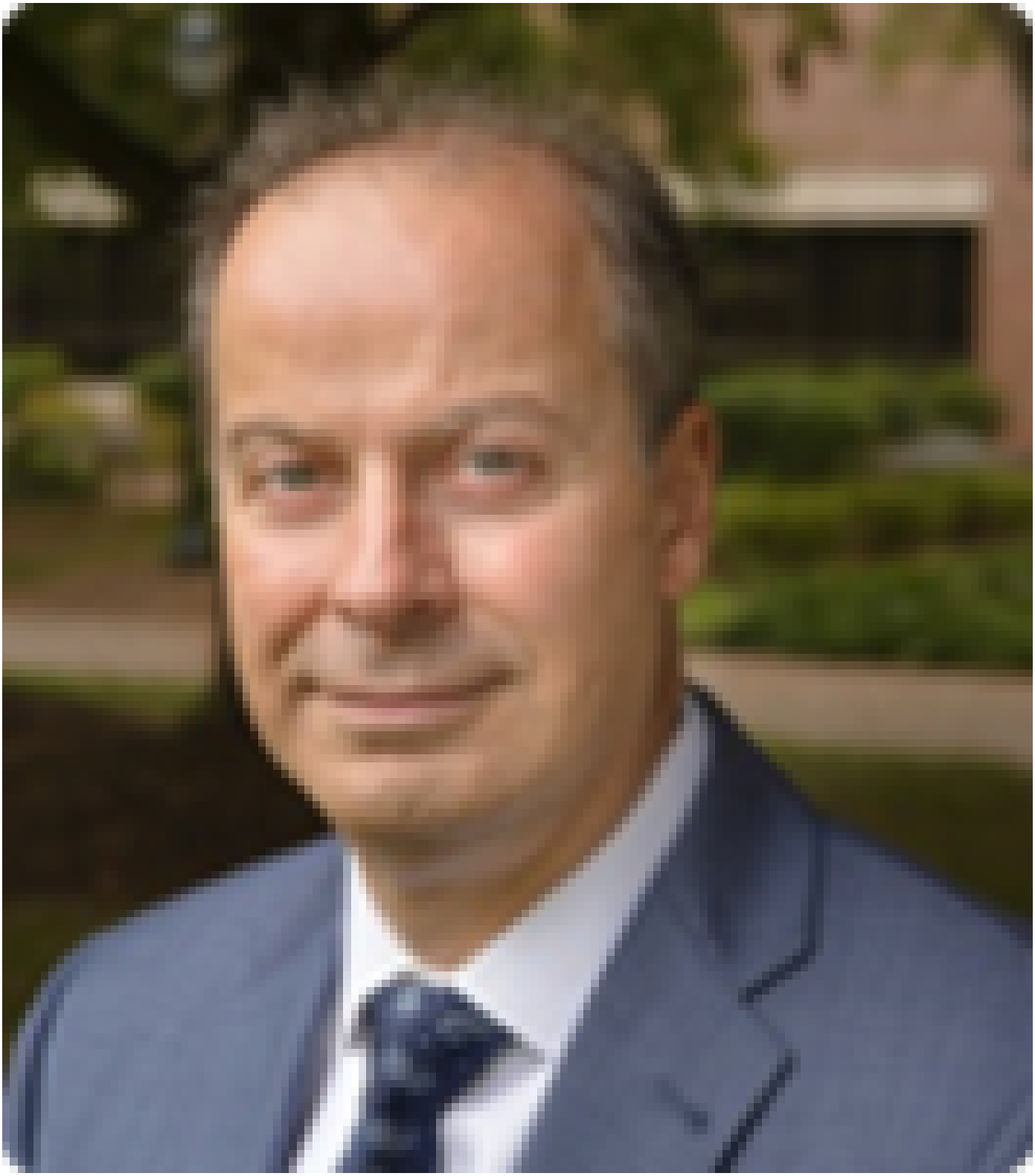

Luzsana CEO Scott Filosi (top) and CMO Joseph Eid (photos courtesy of Luzsana)

The main goal, Filosi said during the interview, is to develop the assets cost-effectively because Luzsana "doesn't have to carry the cost" and to raise the standard of care. Jiangsu Hengrui is uniquely positioned in its approach and the company is both lean and efficient, with its global ambitions first focusing on the US market and thereafter on other major markets including Japan and the rest of the world.

Going global is a major theme for the Chinese pharma sector but the journey west has not always been easy. Many companies have relied on partnering with established US firms but Jiangsu Hengrui has chosen to rely only on itself and to take a "focused" approach. (Also see "*Hengrui Takes Focused Approach Amid China Inc's Global Drive*" - Scrip, 23 Dec, 2021.)

The Liangyungang, Jiangsu province-based company had a tough year in 2021, with the gross market value of the Shanghai-listed firm slumping by 48% as of 22 December 2021 to CNY317.6bn ($49.9bn) versus its all-time high set in January last year. China's volume-based procurement scheme and reimbursement price negotiations have seen some large price cuts for anticancers and other widely prescribed drugs from China's largest innovative drug firm.

Recently, several other innovative Chinese pharma companies have been dealt high-profile setbacks in their efforts to get new drugs approved in the US. *Innovent Biologics, Inc.*, along with partner *Eli Lilly and Company*, and *Shanghai Junshi Biosciences Co., Ltd.* with *Coherus BioSciences, Inc.*, both saw their anti-PD-1 immuno-oncology drugs rejected by the US Food and Drug Administration. The Complete Response Letters have stirred up broader concerns around relying on country-specific data for such regulatory approvals.

During the interview, the Luzsana executives also emphasized that the company believes in data-driven prescriptions, data quality and best practice for prescription drugs in the US, and that there should be no difference between data generated inside and outside the country.

Previously, Jiangsu Hengrui has partnered with *Elevar Therapeutics, Inc.* for rivoceranib, which was co-developed in China and with Elevar globally. The combination of camrelizumab and rivoceranib will need to obtain both a new drug approval for the small molecule component and a biologics licensing approval (BLA) for the PD-1 inhibitor.

Going Global Gets Stuck, Chinese Drug Makers CRL Show What Not To Do

By Brian Yang

06 May 2022

Chinese drug makers have more to lament and plenty to learn from as Junshi, HutchMed follow Innovent Bio with FDA rejections. A holistic not opportunistic approach is needed, one ex-FDA expert suggests.

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With global expansion in sight, the Chinese group now has US offices in Princeton, NJ as well as in Tokyo in Japan and Basel in Switzerland. There are over 100 related employees, with plans to more than double this number year-end.

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