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Catchup Capsule: Key APAC Insights You Need To Read

by Ian Haydock

Given its ever-growing role as a critical region for the global biopharma industry, you can't afford not to be up to speed on Asia. This selection of recent insights from our experienced on-the-ground team will help.

A selection of key stories from the past few weeks and new video interview from the Asia-based content team for *Scrip* and the *Pink Sheet*, reflecting the diversity and depth of issues facing the biopharma industry in this critical and fast-changing region.

In this edition: competing stock markets for China's biotechs; <u>Organon</u>'s regional head talks business plans; quality issues persist in China drug applications; India leads world in plasmid DNA coronavirus vaccines; Japan grants first nod globally for new glioma drug; and South Korean firms say how they plan to take part in international COVID-19 R&D activity.

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(Highlighted text provides links to the original story.)

Two Years On, China's STAR Attracts Star Players But With New Hurdles

Created to take on Nasdaq in the US, the Shanghai Stock Exchange's STAR Market is <u>celebrating</u> <u>its two-year anniversary</u> with star performers such as <u>CanSino Biologics Inc.</u> But its viability as an alternative will be tested by <u>BeiGene, Ltd.</u>, which is set to start trading in Shanghai following dual listings in New York and Hong Kong, with the latter continuing to attract other biopharma IPOs, Dexter Yan in Shanghai writes.

Organon APAC Head On Why World Needs A Company Dedicated To Women's Health

Kaja Natland, Organon's head for the Asia Pacific region including Japan, tells Scrip's Mumbai-

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based Anju Ghangurde *in this audio interview* why the world needs a specialist women's health company, underscoring there's no other healthcare firm with the kind of global footprint that the Merck & Co. spin-out brings and which is dedicated to "putting women at the center."

Study Flaws, Data Integrity Issues Clog China Review System As Applications Soar

To find how prevalent problems are in regulatory filings in China, one doesn't have to read far within the country's annual report on new drug reviews released by the National Medical Products Administration. Last year, the regulatory agency approved 20 innovative new products and 72 imported drugs (including additional indications), but problems persist with the quality of filings, *Brian Yang in Beijing reports*. (This *Pink Sheet* article has been made free access with registration.)

World A Step Closer To First Human Plasmid DNA Vaccine As Zydus Seeks EUA

A plasmid DNA vaccine for human use has moved a step closer to reality, with India's <u>Zydus</u> <u>Cadila</u> applying for an accelerated nod for its COVID-19 candidate in India, which is set to be the first worldwide for such a product. Interim Phase III efficacy and inclusion of the Delta variant in the trial imply better odds for approval, <u>Vibha Ravi in Mumbai writes</u>.

Pioneering Japan Approval For Daiichi's Oncolytic Virus In Glioma

Japan has *granted the first approval anywhere* for an oncolytic virus therapy for use in a form of malignant brain cancer, based on limited Phase II results and conditional on additional data. The authorization for marketing of *Daiichi Sankyo Co., Ltd.*'s Delytact (teserpaturev/G47 delta) in Japan marks the first such approval anywhere of an oncolytic virus therapy for malignant glioma, a form of primary brain cancer, Tokyo-based Ian Haydock writes.

Bio Korea: R&D Strategies To Tackle Global COVID-19 Market

South Korea is lagging behind major countries in the development of COVID-19 therapies and vaccines so how should its firms approach global markets? Participants at the Bio Korea 2021 conference *stressed the need* to obtain manufacturing technology and know-how.

Author Jung Won Shin in Seoul talks about the main findings of her article and how she added value in the short video below. (Also available on YouTube <u>here</u>.)

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