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Asia Deal Watch: Aditum Bio Launches Vitalli To Develop Daewoong Immunology Candidate

by Jung Won Shin

In addition, deals involving Lupin/Medisol, Junshi/Dr. Reddy's, Zai Lab/MediLink, Kyowa Kirin/ADVANZ, Ipca/Unichem, Jiangsu Aidea/Kainos.

Scrip regularly covers business development and deal making in the biopharmaceutical industry. Deal Watch is supported by deal intelligence from Biomedtracker.

Daewoong, Vitalli Ink \$447m Autoimmune Disease License Agreement

Daewoong Pharmaceutical Company Ltd. said on 28 April that it has reached a global out-licensing agreement with Vitalli Bio, a subsidiary of US investment firm Aditum Bio, for the Korean pharma's autoimmune disease drug candidate DWP213388, in a deal worth as much as \$477m, including an upfront payment of \$11m. DWP213388 a highly selective dual inhibitor of interleukin-2-Inducible T-Cell Kinase (ITK) and Bruton's tyrosine kinase (BTK).

In tandem with the deal announcement, Aditum revealed the formation of Vitalli, a portfolio company created for the development of novel therapies for immunological disorders. After the licensing deal closes, DWP213388 will be renamed VIT-801 and is anticipated to enter Phase I studies in 2023.

Unlike current treatments, which are generally limited to inhibiting only individual cell types, VIT-801 is a dual-target inhibitor that simultaneously inhibits B-cells, T-cells and other immune cells, potentially providing a best-in-class profile in immune disorders where multiple cell types are implicated. In addition to VIT-801, Vitalli Bio will get an option to license earlier-stage dual-target inhibitors in development by Daewoong.

Vitalli is the ninth company launched by Aditum Bio, founded by former Novartis AG CEO Joe

Jimenez. To speed these drugs to market, Aditum Bio fosters an incubator model, focusing on the translational phase of drug development. (Also see "[Finance Watch: Joe Jimenez Ventures Into Start-Up World Via Aditum](#)" - Scrip, 2 Nov, 2020.) Aditum said its "spinout" model enables a nimble, start-up culture with a dedicated team of managers supported by an in-house team of operational and technical area experts, ranging from nonclinical pharmacology and CMC to regulatory affairs and clinical operations.

Lupin To Expand Injectables Portfolio Via Medisol Acquisition

[Lupin Limited](#) is acquiring the entire share capital of the French generics injectables maker Medisol, in a bid to expand its market share in the lucrative injectables segment. The acquisition, announced on 5 May, will give the Indian company access to Medisol's seven injectables in France, the second-largest market in Europe for this category of drugs.

Lupin has been expanding its global presence and was involved in four acquisitions last year, adding to its portfolio brands from [Bausch + Lomb Inc.](#), Anglo French Drugs & Industries, [Boehringer Ingelheim GmbH](#) and [Sunovion Pharmaceuticals Inc.](#) (Also see "[India M&As Overtook PE Activity In 2022, Deal Momentum To Continue In 2023](#)" - Scrip, 25 Jan, 2023.)

The products acquired from Medisol are spread across four therapeutic areas of cardiovascular disease, pain management, anti-inflammatory and obstetrics. Medisol, established in 2011, has developed and commercialized its portfolio in pharmacies and hospitals.

Junshi, Dr. Reddy's Jointly Develop And Commercialize Toripalimab

[Shanghai Junshi Biosciences Co., Ltd.](#) is teaming up with [Dr. Reddy's Laboratories Ltd.](#) to jointly develop and commercialize PD-1 checkpoint inhibitor toripalimab in Latin America, India and South Africa, as well as the optional markets of Australia, New Zealand and nine other countries, in a licensing deal worth up to \$728.3m, according to the companies on 7 May.

Junshi will grant a license to Dr. Reddy's to develop and exclusively commercialize toripalimab in Brazil, Mexico, Colombia, Argentina, Peru, Chile, Panama, Uruguay, India and South Africa. Dr. Reddy's may elect to expand the license to cover Australia, New Zealand and nine other unidentified countries. Additionally, Junshi granted Dr. Reddy's the exclusive right of first negotiation to commercialize two other unnamed products in one or more countries within the total 21 countries of Dr. Reddy's territory.

Junshi Biosciences can realize up to a combined \$728.3m comprising the upfront payment, potential expansion of Dr. Reddy's territory and related milestone payments, plus double-digit percentage royalties on net sales of products containing toripalimab.

Zai Lab Obtains Global Rights To MediLink's Preclinical DLL3-Targeting ADC

Hong Kong-listed [Zai Lab Ltd.](#) has obtained exclusive global rights to develop and commercialize MediLink Therapeutics' delta-like ligand 3 (DLL3)-targeting antibody-drug conjugate YL212 for an undisclosed amount, the companies announced on 27 April. YL212 has demonstrated an encouraging preclinical profile, the companies said. DLL3 is an inhibitor of the Notch ligand that is overexpressed in small cell lung cancer (SCLC) and neuroendocrine tumors.

Suzhou, China-based MediLink will be eligible to earn undisclosed upfront fees and development and sales-based milestone payments, as well as tiered royalties on global annual net sales of YL212 and potential third-party sublicensing payments.

Kyowa Licenses Global Rights For Hypogonadism Drug To Advanz

[ADVANZ PHARMA Corp](#) inked an agreement on 25 April with [Kyowa Kirin Co., Ltd.](#) conferring global rights to the latter's Tostran, a transdermal, once-daily, 2% gel formulation of testosterone, used for treating men with hypogonadism, who display associated clinical signs and symptoms of testosterone deficiency, such as fatigue, depression, decreased libido and loss of muscle mass.

Tostran (also branded as Tostrelle for female sexual dysfunction) was developed originally developed by [Cellegy Pharmaceuticals](#) (now [Adamis Pharmaceuticals Corp.](#)), which subsequently licensed global rights to [ProStrakan Group plc](#) under a 2006 deal. Kyowa Kirin then acquired ProStrakan in 2011. (Also see "[Kyowa Hakko Kirin Of Japan To Acquire ProStrakan Of U.K.](#)" - Scrip, 22 Feb, 2011.)

Under a 2009 deal, [Endo International plc](#) obtained exclusive US marketing rights to the therapy, which was launched in the US in 2014 as an authorized generic (sold under the brand name Fortesta). (Also see "[Endo signs \\$210 million Fortigel deal with ProStrakan](#)" - Scrip, 27 Aug, 2009.) Advanz said the current deal will further strengthen its specialty pharmaceuticals portfolio and support its growth in Europe.

Tostran is currently marketed as Fortigel in the US and across Europe, including Sweden, where it's sold as Tostrex. Advanz plans to leverage its existing specialty pharmaceutical infrastructure to ensure continued patient access.

Ipcia Makes Majority Stake Acquisition In Unichem

[Ipcia Laboratories Ltd.](#), which has three of its facilities under an import alert from the US Food and Drug Administration (FDA), plans to acquire a majority stake in Unichem Laboratories in a move to gain access to the latter's FDA-compliant finished dosage-manufacturing units.

The FDA temporarily lifted the alert in March 2020 when the US needed to stock hydroxychloroquine sulphate tablets, considered a COVID-19 prophylactic and treatment at the time. However, the relaxation was lifted in June once the supply shortage ended. (Also see

"[Indian Industry Gets HCQ, Paracetamol Exports Rolling](#)" - Pink Sheet, 15 Apr, 2020.) (Also see "[FDA 'Exception' For Ipca's Chloroquine/HCQ Amid Supply Plans From Others](#)" - Pink Sheet, 24 Mar, 2020.)

Ipca previously acquired sales and distribution company Bayshore Pharmaceuticals as well as also active pharmaceutical ingredients (API) maker Pisgah Labs in the US. (Also see "[Ipca Takes Full Ownership Of Bayshore](#)" - Generics Bulletin, 1 Oct, 2021.)

The latest deal, announced on 24 April, will bring into its fold finished dosages units in Goa and Ghaziabad, India, both of which comply with US FDA norms. Unichem derived about 58% of its FY22 sales from the US generics market and has 76 abbreviated new drug applications (ANDAs).

Ipca will acquire a 33.38% stake in Unichem from Prakash Amrut Mody – one of its founders – for INR10.3bn (\$126.3m) at INR 440 per share, with Mody retaining a 12.78% stake. It is also making an open offer at INR 440 per share for an additional 26%.

In a discussion with analysts, management termed Unichem's formulation facilities "excellent," with a proven quality record, adding that the company offers differentiated, complementary capabilities. However, investors and analysts remained skeptical of the acquisition, widely seen as overpriced, with the offer price representing a 17% premium to Unichem's pre-announcement share price of INR 377.2.

Kainos, Jiangsu Aidea Ink Global HIV Licensing Agreement

[Kainos Medicine, Inc.](#) unveiled an exclusive global out-licensing of its novel HIV drug KM-023 with China's [Jiangsu Aidea Pharmaceutical Co Ltd](#) on 21 April. Financial terms weren't disclosed.

The agreement, which excludes China, Taiwan and Hong Kong as well as South Korea, comes after the two already reached a license agreement to develop and commercialize the novel non-nucleoside reverse transcriptase inhibitor (NNRTI) in China, Taiwan and Hong Kong in 2014. The HIV drug gained marketing authorizations in China in 2021 as a drug complex and in 2022 as a single tablet in China.

Jiangsu Aidea said it aims to pursue sales of the product in South Africa, South America, India and China using state-procurement projects and will seek entry into European markets as well.

Stay tuned for the next edition of Asia Deal Watch. You can read more about other deals that have been covered in depth by Scrip and Generics Bulletin in recent days below:

(Also see " <u>Can BlissBio's HER2-Targeting ADC</u>	A new deal worth up to \$2bn-plus with Eisai has put Bliss Biopharmaceutical's HER2-
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<p><u>Challenge Enhertu In Breast Cancer?</u>" - Scrip, 10 May, 2023.)</p>	targeting antibody-drug conjugate BB-1701 in the spotlight, as the global race heats up to find a possible challenger to Enhertu.
<p>(Also see "<u>Opportunities Amid Crisis: Junshi, Allist Look To Expand Pipelines Through Alliances, M&A</u>" - Scrip, 9 May, 2023.)</p>	Against the prevailing headwinds in the biotech sector, two Chinese firms are bucking the trend of pipeline reorganization by eyeing the potential acquisition of assets from external partners to expand into more modalities and therapeutic areas.
<p>(Also see "<u>Time To Grow: SK Bioscience Eyes US Vaccine, CGT Acquisitions This Year</u>" - Scrip, 4 May, 2023.)</p>	SK Bioscience CEO outlines the progress the firm is making in its growth acceleration strategy, which involves aggressive M&As and other investment plans.
<p>(Also see "<u>Lilly Migraine Deal Gives AffaMed New Mojo In Changing China: Video Interview</u>" - Scrip, 3 May, 2023.)</p>	A mega deal with Eli Lilly to exclusively market, promote and distribute Emgality (galcanezumab) in China for migraine prevention offers a critical opportunity for C-Bridge backed AffaMed in an untapped, large market, CFO Vijay Kawal told <i>Scrip</i> in an exclusive video interview on the sidelines of EBD's Asia Bio Partnering Forum.
<p>(Also see "<u>Astellas Paying \$5.9bn For Iveric To Boost Ophthalmology Presence</u>" - Scrip, 1 May, 2023.)</p>	Astellas set to acquire private US firm Iveric to add to its strategic capabilities in ophthalmology focus area, along with another revenue pillar as it prepares for Xtandi expiry.
<p>(Also see "<u>2022 Deal-Making Snapshot: One Big Deal Didn't Change The Downward Trends</u>" - Scrip, 21 Apr, 2023.)</p>	Even with Amgen's \$27.8bn acquisition of Horizon in mid-December, biopharma M&A volume, total value and average deal value all dropped substantially from 2021.