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NEWS LETTER
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## Sun Pharma Offers More To Buy Out Israeli Company Taro Pharma


Drugmaker Sun Pharmaceutical Industries has upped its offer to mop up additional shares in Israeli arm Taro Pharmaceutical Industries, six months after its earlier proposal. Taro's special committee evaluating the proposal has agreed in principle to the revised proposal and to negotiate definitive agreements, Sun Pharma said, adding however that there was no assurance on achieving this.

The May offer had been opposed by Krensavage Asset Management LLC, the largest minority shareholder in Taro Pharma. "Sun's inadequate offer amounts to a 17 per cent discount to the value of Taro's tangible assets, namely $36 a share of net cash. If Taro liquidated, shareholders could receive more than $45 a share," Krensavage said.

On May 26, 2023, Sun Pharma delivered to the board of directors of Taro Pharma a letter containing a non-binding indication of interest to acquire all outstanding ordinary shares in Taro, other than those held by Sun or its affiliates, at $38 per share in cash, Sun Pharma said on Tuesday. "Subsequently.

The company engaged in multiple rounds of price negotiations with a special committee of the board of directors of taro regarding the proposal. Such negotiations resulted in the company communicating to the special committee updated terms pursuant to which the company has proposed to acquire all of the outstanding shares of Taro's ordinary shares... for a purchase price of $43 per share in cash," Sun Pharma told the stock exchanges.

"On December 10, 2023, the special committee confirmed that it agreed in principle with the revised proposal and that it has agreed to negotiate definitive agreements," it said, adding that negotiations on the definitive terms and agreements for the revised proposal were ongoing, and there were no assurances that a definitive agreement would be reached.

The special committee consists of only independent directors; the required corporate approvals for the proposed transaction shall include the affirmative approval of Taro shareholders holding a majority of the votes, it added. Sun's latest offer to buy out and delist Taro from NYSE comes 10 years after its previous effort was terminated. In 2007, Sun had made a $454-million offer for Taro — a deal it sealed after the two companies fought a long cross-country battle. Then, too, Sun's efforts to mop up the outstanding shares ran into resistance from a section of minority shareholders. With about 66 per cent in Taro, Sun eventually abandoned a sweetened proposal to mop up the remaining shares in 2013. (Source: Business Line)

## India Bans Anti-Cold Drug For Children Below 4 After Syrup Deaths Claim

The drugs regulator in India has banned the use of an anti-cold drug combination in children aged below four and ordered that drugs should be labelled accordingly, in the wake of the deaths of at least 141 children globally linked to cough syrups.

The regulator said concerns raised about promotion of an unapproved anti-cold drug formulation in infants prompted a discussion and a resulting recommendation to not use the combination for that age group.

The order comes after a spate of child deaths since 2019 that authorities linked to toxic cough syrups made in the country, including at least 141 deaths in Gambia, Uzbekistan and Cameroon since the middle of last year. Within India, authorities said at least 12 children died and four others were left with severe disabilities in 2019 after consuming domestically-made cough syrups. India is often dubbed the "world's pharmacy" due to its supply of life-saving drugs at low prices.

The order by the regulator on the fixed-drug combination (FDC), issued on Dec. 18 and made public on Wednesday, requires drugmakers to label their products with the warning that the "FDC should not be used in children below 4 years of age". The fixed drug combination comprises chlorpheniramine maleate and phenylephrine - medication that is often used in syrups or tablets to treat common cold symptoms.

The World Health Organization does not recommend the use of over-the-counter cough syrups or medicines for the treatment of coughs and cold symptoms in children younger than five years of age. Authorities here have introduced mandatory testing for cough syrup exports since June and stepped up scrutiny of drugmakers. Drugmakers whose cough syrups were linked to child deaths have denied any wrong doing. (Source:NDTV)

## Sun Pharma To Buy 16% Stake Of Lyndra Therapeutics For ₹249 Crore


The acquisition is a strategic investment to support the development of innovative pharmaceutical delivery technologies and get access to the technology for certain molecules and territories.

Sun Pharmaceutical Industries has agreed to acquire about 16.7 percent in Massachusetts-based Lyndra Therapeutics Inc, engaged in developing novel delivery technology for long-acting oral (LAO) therapies, for $30 million (₹249 crore).

The acquisition is a strategic investment to support the development of innovative pharmaceutical delivery technologies and get access to the technology for certain molecules and territories, Sun explained in a statement to the BSE, Monday. Sun expects the transaction to be completed by end-December 2023, subject to certain conditions.

Lyndra was incorporated on January 14, 2015 and its revenues over the last three years, (January-December), have been reducing from $ 25.6 million (2020) to $ 13.1 million (2021) to $ 10.7 million (2022). In July, Lyndra had announced certain management changes, including elevating long-time executive President and Chief Operations Officer Jessica Ballinger as its President and Chief Executive Officer.

Explaining its trademarked Lyndra's LYNX drug delivery platform, the company had then said, it was a significant advance in oral drug delivery in decades, creating medicines that last for a week or longer in an oral dosage form.

"A key aspect of the platform is its ability to deliver the drug consistently, minimising peaks and troughs of drug levels compared to daily medicine," Lyndra said. Based on technology invented in the Langer Lab at MIT, the LYNX platform has progressed rapidly since 2015 through preclinical and early human studies and achieved proof of concept of the platform and lead asset in a Phase 2 study, it added.

"The LYNX drug delivery platform has the potential for broad applicability across multiple therapeutic areas – including approved drugs and those currently in development," it said, adding that it facilitated increased adherence and improved health outcomes while freeing people from the burden of daily pills and simplifying their lives, it said. (Source: Business Line)

## Lupin's Swiss Subsidiary To Acquire Established Products in Europe, Canada From Sanofi, for ₹91 Crore


Drugmaker Lupin said its Swiss subsidiary, Lupin Atlantis Holdings SA, had signed an Asset Purchase Agreement with French multinational Sanofi to acquire a portfolio of established products in Europe and Canada.

The company said it was acquiring brands AARANE in Germany and NALCROM in Canada and the Netherlands. The purchase consideration was €10 million (₹91 crore), besides sales milestones up to €8 million (₹72 crore), dependant on future sales, it said. The turnover of the brands in these markets for the year ended March 31, 2023 was about $6.494 million (₹53 crore), Lupin said.

The brands being acquired will strengthen Lupin's respiratory segment, the company said. It would help structure the new respiratory franchise in Germany following the launch of Luforbec; the launch of Gx Spiriva and the acquisition of Xopenex and Brovana in the United States, it added. The transaction will require approval from the Foreign Direct Investment Bureau of Canada, Lupin said, adding that the acquisition was expected to be completed by the first quarter 2024. (Source: Business Line)

## US FDA Puts Clinical Hold On Iovance's Cancer Therapy Trial

The U.S. health regulator has placed a clinical hold on Iovance Biotherapeutics' (IOVA.O) trial of its experimental cell therapy in lung cancer patients after a patient death, the company said on Wednesday, sending its shares down about 20%. The company will pause enrollment in the non-small cell lung cancer (NSCLC) trial during the hold, while patients who were previously treated with the therapy will continue to be monitored.

The hold placed by the Food and Drug Administration (FDA) could potentially delay the therapy trial by months, analysts estimated, marking a setback to Iovance's quest to develop a new type of therapy for NSCLC, which is the most common form of the disease. The therapy, called LN-145 TIL, which is also being developed to treat melanoma, uses white blood cells from a patient's tumor, modifies them and puts them back into the patient to help the immune system destroy cancer cells.

Beyond the time it takes to actually resolve the clinical hold, it is possible that (the) hold results in recruitment losing momentum, potentially exacerbating the delay to data," said Truist analyst Asthika Goonewardene in a client note. The company said the death was potentially related to a pre-conditioning regimen, where the patient receives a short course of chemotherapy to kill immune cells before being infused with Iovance's therapy.

The FDA's hold has no impact on any other trials conducted by the company, including a melanoma study, the company said. The hold raises concerns that it could impact the marketing application in melanoma, Mizuho analyst Mara Goldstein said, though the company has indicated no impact. The FDA had extended review of the skin cancer therapy from November to Feb. 2024, due to resource constraints. (Source: Reuters)

## AstraZeneca To Buy China's Gracell Biotechnologies In $1.2 Billion Deal


AstraZeneca (AZN.L) said on Tuesday it will buy Gracell Biotechnologies (GRCL.O) for up to $1.2 billion as the Anglo-Swedish pharma company furthers its cell therapy ambitions and boosts its presence in China, the world's second-largest pharmaceuticals market.

The cash deal, which adds several experimental therapies to AstraZeneca's portfolio, values Gracell at $2 per ordinary share, or $10 per American Depository Share, of Gracell, representing a premium of 61.6% from its last close on Dec. 22.

The shareholders will also receive a non-tradable contingent value right of $0.30 per ordinary share, if certain regulatory milestones are met. Shares of China-headquartered Gracell surged 60% in premarket trading in the United States. Gracell's CAR-T cell therapy works by extracting disease-fighting white blood cells known as T-cells from a patient, re-engineered to attack cancer and infused back into the body. Advertisement.

Scroll to continue H.C. Wainwright analyst Emily Bodnar said this could be AstraZeneca's way of getting more into cell therapy as it is not as heavily involved in the space like Novartis (NOVN.S) and Gilead (GILD.O).

AstraZeneca will also acquire Gracell's cash, cash equivalents and short-term investments of $234.1 million as of Sept. 30, 2023. The deal is expected to close in the first quarter of 2024, according to the statement. AstraZeneca.

One of the biggest drugmakers in China, had drafted plans to spin off its business in the region, according to media reports in June. Last month, AstraZeneca agreed to a licensing deal for an experimental anti-obesity pill from China's Eccogene, and in August it announced a contract manufacturing deal with CanSino Biologics for its messenger RNA technology vaccine program.

AstraZeneca signed three licensing deals with Chinese companies, CEO Pascal Soriot said earlier this year. Reporting by Urvi Dugar and Christy Santhosh in Bengaluru; Editing by Sonia Cheema, Nivedita Bhattacharjee and Krishna Chandra Eluri (Source: Reuters)

## US FDA Approvals Bounce Back In 2023, Sparking Hopes Of A Biotech Recovery


The U.S. Food and Drug Administration approved nearly 50% more novel drugs in 2023 than in 2022, putting it back on pace with historical levels, an improvement analysts and investors said could lead to increased investment in biotech firms.

FDA nods for innovative therapies containing an active ingredient or molecule not previously approved, rose to 55 in 2023, up from 37 in 2022 and 51 in 2021. Historical data shows the FDA typically green lights about 45-50 new drugs a year and hit a peak of 59 in 2018.

The agency approved several high-profile therapies such as Eli Lilly's (LLY.N) obesity drug Zepbound and Eisai (4523.T) and Biogen's (BIIB.O) Alzheimer's treatment Leqembi. It also approved five gene therapies in addition to the 55 novel drugs, including a sickle cell disease treatment from Vertex Pharmaceuticals (VRTX.O) and CRISPR Therapeutics (CRSP.BN) using the latter's innovative gene editing technology.

"It is good to see the FDA approvals go up," said John Stanford, executive director of Incubate, a Washington-based group of life sciences investors. He called the advance of gene editing technology particularly encouraging.

"Our scientists can do a lot more, and from that perspective we are excited about what's coming down the pipeline, not just in 2024, but beyond that," he said.

The FDA in a statement said, "the number of novel drugs approved varies from year to year, and may be due to a variety of factors." Those include the complexity of new drugs in development as well as advances in scientific understanding of diseases and disease targets, it said.

The agency did not provide a specific reason for the big drop in approvals in 2022. TD Cowen analyst Ritu Baral said the COVID-19 pandemic was likely a factor. When the pandemic hit, the agency moved from approving drugs at record pace to operating with a remote workforce, which caused disruption and issues such as delayed inspections that affected drug reviews.

"We're back at those peak levels, which hopefully means that the workflow disruptions, staffing and bandwidth issues and, most importantly, communications with developers, have hopefully been improving, Baral said, adding that she expects a similar level of FDA approvals in 2024.

**INVESTMENT DECLINES**

Investment in biotech companies over the past two years has been a fraction of historical levels. After 108 initial public offerings (IPOs) in 2021, there were only 18 each in 2022 and in 2023 as of mid-December. A basket of biotech-focused funds tracked by Piper Sandler saw $15.8 billion in capital outflow in 2023, the largest ever going back to 1992, according to the brokerage.

"2023 has been a year where the market was selective in the companies able to access capital," William Blair analysts said in a December note. They noted that companies developing GLP-1 weight-loss treatments, the same class as Novo Nordisk's wildly popular Wegovy and Lilly's Zepbound, have had better access to the IPO market.

Industry analysts also said lingering investor concern about high interest rates and government scrutiny of drugmakers could hamper a full funding recovery.

"While we don't expect capital markets to return to peak 2020-21, we do think that conditions will improve and that the window will open up," Jefferies analyst Michael Yee said. Incubate's Stanford said some investors may remain on the sidelines due to increased oversight of deals in the sector, the government's drug price negotiation plans and the threat that the Biden administration is looking to seize patents of medicines developed with government funding if the prices are deemed to be too high. (Source: Reuters)