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Deal Watch: Gilead Acquires Xilio's IL-12 Activating Candidate

by Joseph Haas

Plus deals involving Avalo/AlmataBio, AbbVie/Parvus, NovaBay/Eyenovia, Bayer/Aignostics, Merck & Co./Pearl, tech transfer agreements and deals in brief.

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

Gilead Gets Xilio's Phase I Cancer Drug, Aims To Turn 'Cold' Tumors 'Hot'

Gilead Sciences, Inc. obtained exclusive rights on 28 March to develop and sell *Xilio Therapeutics, Inc.*'s Phase I tumor-activated IL-12 program, XTX301. Now in a Phase I open-label trial in solid tumors, the candidate is designed to stimulate anti-tumor immunity and reprogram the tumor microenvironment of poorly immunogenic "cold" tumors towards an inflamed or "hot" state susceptible to immuno-oncology treatment.

Gilead paid $43.5m up front under the deal, including $30m in cash and a $13.5m investment in the Waltham, MA-based firm. The equity agreement transferred 6.86 million shares at $1.97 each, a 190% premium. In addition to the upfront equity purchase, Xilio can direct Gilead to purchase up to $11.5m of its stock through three further equity placements.

Xilio will continue clinical development of XTX301 in an ongoing Phase I clinical trial through an initial planned Phase II dose-expansion. Following delivery by Xilio of data related to the Phase I and planned Phase II trials, Gilead can elect to takeover development and commercialization of XTX301 in exchange for a $75m transition fee. Additionally, Gilead will be on the hook for $17.m in near-term milestone payments, $500m in additional development, regulatory and commercialization milestones, and tiered sales royalties.

Gilead told *Scrip* it primarily wants to investigate XT301's potential as a monotherapy, and

thinks it may offer utility in both hot and cold tumors. Beyond monotherapy development, the company is considering the candidate's potential for combination development with zimberelimab, its anti-PD-1 agent currently in Phase III for gastric cancer and Phase II for lung and prostate cancer. It is also approved in China under the brand name YuTuo for cervical cancer.

But Xilio told *Scrip* it thinks "XTX301 has broad combination potential which could include checkpoint inhibitors such as CTLA-4 and PD-(L)1 as well cell engagers." The company added that it thinks activation of IL-12 could work where other approaches have failed in the effort to make cold tumors respond to immuno-oncology therapies. Xilio grossed $117.6m in an initial public offering in October 2021. (Also see "*Finance Watch: Four New IPOs Hold Steady In First Days Of Trading*" - Scrip, 22 Oct, 2021.)

Avalo Builds Pipeline With AlmataBio Acquisition

Avalo Therapeutics, Inc. , focusing on therapies that address immune dysregulation, acquired privately held AlmataBio in an all-stock transaction on 27 March. Atlanta-based AlmataBio was founded in April 2023 primarily to in-license and develop AVTX-009, an anti-IL-1β mAb originally developed by *Eli Lilly and Company*.

AVTX-009 is ready to begin a Phase II trial in hidradenitis suppurativa (HS) with top-line data anticipated in 2026. Inhibition of IL-1β could offer potential in HS and a variety of inflammatory diseases in dermatology, gastroenterology, and rheumatology, Avalo said. The Rockville, MD, biotech said intends to develop AVTX-009 in at least one other chronic inflammatory indication.

Under the agreement, Avalo issued AlmataBio stockholders an aggregate of 172,000 of its common shares and an aggregate of 2,400 shares of Series C non-voting convertible preferred stock, valued at approximately $15m total. In addition, Avalo will pay up to $27.5m in earnouts, including $5 due upon initiation of the Phase II trial in HS, and $15 when the first patient is dosed in a Phase III trial for any indication.

AlmataBio shareholders also received a $7.5m payment upon the closing of Avalo's private placement financing, conducted concurrent with the acquisition, netting $105m. Formerly known as Cerecor, Avalo said the deal will enhance its pipeline, which includes quisovalimab (AVTX-002), an anti-LIGHT mAb in Phase II for ulcerative colitis, and AVTX-008, a preclinical BTLA agonist fusion protein for autoimmune disease. (Also see "*Cerecor Turns The LIGHT Back On As Avalo, With PRV Haul In Sight*" - Scrip, 27 Aug, 2021.)

AbbVie Offers $137.5m For Landos, Plus Potential CVR Payout

AbbVie Inc. announced that it will acquire autoimmune disease-focused *Landos Biopharma, Inc.* through a definitive merger agreement on 25 March. Under the deal, AbbVie will acquire Landos

at a price of $20.42 per share (a 198% premium) in cash upon closing, approximately $137.5m, plus contingent value rights (CVRs) worth roughly $75m.

Landos shareholders will receive one non-tradable CVR per share with a value of up to $11.14 per share, subject to the achievement of a clinical development milestone. The proposed transaction is expected to close in Q2, subject to approval by Landos' stockholders.

Founded in June 2017, Landos has developed a pipeline of targets anchoring two libraries of immunometabolic-modulation pathways, including four oral candidates targeting multiple indications in the immunology space. (Also see "*Landos Leverages Advanced Computing For Autoimmune Disease Drug Development*" - Scrip, 11 Jan, 2019.) Its lead pipeline asset is NX-13, a first-in-class, oral NLRX1 agonist with a bimodal mechanism of action in Phase II for ulcerative colitis.

Landos's pipeline also includes preclinical candidates LABP-66 for multiple sclerosis and neurodegenerative disorders and LAPB-73 for asthma and eosinophilic disorders. Both are in the pre-investigational new drug (IND) stage, according to Landos.

AbbVie Gets Option To Worldwide Rights For Parvus Treg Candidates

The week before unveiling its Landos takeout, AbbVie partnered with *Parvus Therapeutics Inc.* to use the latter's Navacim regulatory T-cell (Treg) technology platform to develop novel therapies for inflammatory bowel disease indications under an exclusive worldwide collaboration and option agreement. AbbVie will get the option to develop and commercialize Navacim candidates developed by Parvus under the agreement announced on 20 March.

Specific financial details were not revealed but Parvus said it will get upfront cash, a "potential" equity investment from AbbVie and the opportunity to earn development and commercial milestones as well as sales royalties.

Parvus, which has previously partnered the Navacim technology with *Genentech, Inc.* and *Novartis AG*, said the platform is an immune-tolerization technology that can present multivalent peptide major histocompatibility complexes to trigger endogenous expansion and differentiation of T-cells into antigen-specific Tregs. (Also see "*Keytruda Rules The Roost, But Merck & Co. Highlights Progress In Other Areas* " - Scrip, 20 Jun, 2019.) The goal is to restore organ-specific immune tolerance without compromising normal immunity, the South San Francisco biotech said.

NovaBay, Eyenovia To Promote Each Other's Ophthalmic Products

NovaBay Pharmaceuticals, Inc. and *Eyenovia, Inc.* unveiled a co-promotion agreement on 13 March to commercialize prescription ophthalmic products to US eyecare professionals.

Under the agreement, NovaBay will market Eyenovia's Clobetasol (clobetasol propionate ophthalmic suspension 0.05%), a steroid approved to treat inflammation and pain following ocular surgery, through its US physician-dispensed channel. Meanwhile, Eyenovia will market NovaBay's prescription Avenova Antimicrobial Lid & Lash Solution for blepharitis and dry eye disease through its US sales force, which markets Clobetasol.

Clobetasol propionate ophthalmic suspension 0.05%, developed by *Formosa Pharmaceuticals Inc.*, got US Food and Drug Administration approval on 4 March; it is expected to receive a tradename as soon as this summer, according to Eyenovia. (Also see "*Marching On: Eight Novel Agents Among March Goal Dates For US FDA*" - Pink Sheet, 5 Mar, 2024.) Eyenovia acquired US commercial rights to the product from Formosa last August. (Also see "*Deal Watch: Leo Pharma Adds Rare Dermatology Disorder Candidate In Timber Buyout*" - Scrip, 21 Aug, 2023.)

Then, on 14 March, NovaBay agreed to sell its DERMAdoctor skincare business, including all product inventory, to an undisclosed investor for approximately $1.07m in cash. NovaBay expects the transaction to close this quarter. It originally acquired DERMAdoctor, which commercializes over-the-counter skincare products, in September 2018 for $12m in cash plus up to $3m in earn-out payments. NovaBay said it expects to report net sales for the 2023 fiscal year of $3.6m for 2023 from the business.

Bayer Partners With Aignostics On AI-Driven Oncology Research

Bayer AG and computational pathology-focused Aignostics GmbH announced a multi-year research collaboration on 14 March for precision oncology drug research and development with the application of artificial intelligence. The companies said they will create a novel target-identification platform by combining Aignostics' technology and proprietary multimodal patient cohorts with Bayer's expertise in discovery and R&D expertise in cancer.

Under the agreement, the companies will collaborate on multiple discovery programs and initiate at least two target-identification programs. Berlin-headquartered Aignostics will receive an upfront payment and can earn milestone payments and royalties on any commercialized therapies that result from the collaboration.

The partners said the collaboration will include development of computational pathology algorithms powered by AI and machine learning that will connect baseline pathology data, such as molecular tumor profiles, with clinical data, such as patient outcomes. This effort is expected to enable better patient identification, stratification and selection for clinical trials, identify novel cancer targets with a strong disease link through AI models applied to multimodal patient data, and accelerate clinical development.

Merck To Check Out Pearl's Genomically Recoded Organisms Platform

Synthetic biology company Pearl Bio secured its first major partner on 12 March with *Merck &*

Co., Inc., which will use Pearl's Genomically Recoded Organisms (GROs) technology. The GRO platform pairs genome and ribosome engineering to produce novel biologics with diverse chemistries that previously were inaccessible, the companies said.

The deal could bring Pearl more than $1bn total, including an undisclosed upfront fee plus option and milestone payments. Merck will also pay royalties on sales of any resulting products. Pearl Bio was founded in 2020 and emerged from stealth mode in June 2023. The company is in the process of completing its series A venture funding round.

The collaboration will initially focus on discovery and development of biologic therapies for cancer by leveraging the GRO technology's ability to work in both cell-based and cell-free systems, and with proprietary tethered ribosomes, to encode synthetic monomers and target previously inaccessible epitopes.

Tech Transfer:

- *Metabolon, Inc.* and *Cardiff University* announced a partnership on 12 March to discover new predictive biomarkers to accelerate advancements in the treatment of multiple sclerosis and to inform more personalized care. Focusing on profiling plasma and cerebrospinal fluid samples collected from patients with MS, the collaboration will investigate underlying disease mechanisms and seek to identify new relevant drug targets.

In Brief:

- Vector Pharma FZCO, headquartered in Dubai, signed on to commercialize Stockholm-based *Oncopeptides AB*'s Pepaxti (melphalan flufenamide) in the Middle East and North Africa (MENA) countries of Saudi Arabia, Qatar, UAE, Bahrain, Kuwait, Oman, Algeria, Tunisia, Morocco, Libya, Lebanon and Iraq. Under the agreement announced 27 March, Vector will distribute Pepaxti in the MENA region for the treatment of multiple myeloma. The companies will split all Pepaxti sales revenue in the region, with Vector carrying all costs through its existing infrastructure.

- Paris-based *Juvisé Pharmaceuticals* acquired global commercial rights (excluding the US and Canada) on 26 March to multiple sclerosis drug Ponvory (ponesimod) from *Actelion Pharmaceuticals Ltd.*, a *Johnson & Johnson* subsidiary. To fund the deal, the French sovereign fund Bpifrance and Pemberton Asset Management, a European private credit manager, purchased a minority stake in Juvisé. Financial details of these transactions were not disclosed. Juvisé also will assume worldwide manufacturing duties for Ponvory from sites based in France and Switzerland.

- *Medherant Limited*, developer of the transdermal TEPI Patch delivery technology, inked a collaboration on 25 March with Bayer AG to develop a transdermal patch for delivery of an undisclosed, approved oral medicine. Medherant and Bayer said they have worked on

formulation of the transdermal patch, utilizing Medherant's expertise in laboratory modeling. The collaboration has advanced to the next phase of development, taking the program into non-clinical studies and approaching technology transfer for patch production at Medherant's contract manufacturing partner. Medherant will lead the program through clinical proof-of-concept study completion, after which the companies expect to negotiate a license agreement that will bring Medherant milestone payments and royalties.

- Belgium's *Univercells S.A.* will evaluate use of Bermuda-headquartered *Altamira Therapeutics Ltd.* ' SemaPhore platform in delivery of mRNA vaccines under a collaboration announced 25 March. Univercells will test *in vitro* and *in vivo* a proprietary mRNA vaccine delivered via Altamira's SemaPhore nanoparticle platform. If the experiments succeed, the companies said they intend to negotiate a commercial agreement for development and manufacturing of nanoparticle-based mRNA vaccines using the Univercells technology.

- Chemical and materials firm Celanese Corporation and Germany's *Secarna Pharmaceuticals* signed a collaboration on 20 March to develop long-acting implants that deliver antisense oligonucleotides (ASOs). Combining their technological capabilities, the partners hope to develop ASO-eluting implants for a range of diseases that will offer the potential to reduce dosing frequency, minimize off-target immune responses and improve targeting to provide better patient outcomes. Celanese said its VitalDose drug delivery platform provides reliable, controlled-release performance with a long history of use in approved parenteral drug products in the US and Europe. Secarna said it has validated its ASO platform in cardiometabolic, immuno-oncology, fibrotic/inflammatory and CNS disease settings.

- Stockholm-based *Anocca AB* and *Emendo Biotherapeutics* entered a non-exclusive gene-editing licensing agreement on 14 March to use EmendoBio's OMNI-A4 nuclease to manufacture and develop Anocca's TCR-T cell therapies for difficult-to-treat solid tumors. Anocca said it hopes the EmendoBio technology will enable it to reach more patients faster with personalized treatments targeting the underlying genetic drivers of disease.

- *BioCardia Inc.* and StemCardia announced a long-term partnership on 14 March to advance StemCardia's investigational pluripotent stem cell product candidate SCM-101 for the treatment of heart failure. Under the partnership, BioCardia will be the exclusive biotherapeutic delivery partner for StemCardia's candidate through studies expected to result in FDA approval of an investigational new drug application and anticipated Phase I/II clinical trials to follow.

- UK biotechs *Arecor Therapeutics plc* and TRx Biosciences unveiled a collaboration on 12 March for the formulation development of an oral glucagon-like peptide-1 (GLP-1) receptor agonist product. The companies plan to combine their proprietary technologies to formulate

an oral semaglutide product with enhanced bioavailability using TRx's LipiCore oral delivery technology and Arecor's Arestat formulation technology.

- *Allogene Therapeutics Inc.* and *Arbor Biotechnologies* announced a gene-editing licensing agreement on 12 March that will use Arbor's proprietary CRISPR gene-editing technology in Allogene's next-generation AlloCAR T platform for the treatment of autoimmune disease. Allogene said it has applied its understanding of CAR-T research and development to design next-generation allogeneic CAR-T candidates with a goal of reduced or chemotherapy-free conditioning. Allogene's first investigational product under this program, ALLO-329, is expected to enter Phase I in early 2025.

Stay tuned for the next edition of 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 "*Israel's Gamida Cell Survives By Selling To Lender*" - Scrip, 28 Mar, 2024.)	Having finally secured US approval for Omisirge, Gamida was hoping to bag a strategic partner for the cell therapy. A year on, no suitable partner has been identified and the firm is delisting from the NASDAQ and going private.
(Also see "*Novo Pumps Up Heart Failure Prospects With Cardior Purchase*" - Scrip, 25 Mar, 2024.)	Novo Nordisk is spending some of its semaglutide cash on a mid-stage RNA-based heart failure therapy developed by the German biotech.
(Also see "*Biocon And Eris Strike Indian Deal Over Branded Formulations*" - Generics Bulletin, 20 Mar, 2024.)	Biocon has announced a deal with fellow Indian pharma firm Eris Lifesciences that involves the sale of its local metabolics, oncology, and critical care products while also transferring its employees.
(Also see "*AstraZeneca Pays $2bn To Keep Up With The Joneses*" - Scrip, 19 Mar, 2024.)	Bristol Myers Squibb and Lilly have recently done billion-dollar radiopharmaceuticals deals, and now AstraZeneca wants a piece of the market. But can it make its Fusion fusion work?
(Also see "*Fennec Finds Ex-US Commercial Partner For Pedmark In UK's Norgine*" - Scrip, 18 Mar, 2024.)	Norgine will market Pedmark, indicated to reduce risk of chemotherapy-related hearing loss in pediatric cancer, in the EU and UK. It will seek additional approvals in Australia and New Zealand.
(Also see "*AstraZeneca Spends $800m On*	The Phase III trial of hypoparathyroidism

Amolyt And Awaits A Readout" - Scrip, 14 Mar, 2024.)	asset eneboparatide will have to hit if AstraZeneca is going to carve out market share from Ascendis.
(Also see "*Novartis Goes All In On A Second Long-Term Bet With IFM*" - Scrip, 13 Mar, 2024.)	Novartis partnered with IFM Due in 2019 and has now exercised an option to buy the IFM Therapeutics subsidiary, continuing its ongoing relationship with the group.
(Also see "*Almirall Casts Its Net To Cover Butterfly Skin Disease*" - Scrip, 13 Mar, 2024.)	Almirall is linking up with US biotech Eloxx to get hold of an asset that will be its first in the rare dermatological disease space.