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Deal Watch: BMS Returning IL-12 Candidate To Frequent Partner Dragonfly

by Joseph Haas

The firms' partnership goes back to pre-merger Celgene, and BMS still has Dragonfly candidates in its pipeline. Ji Xing gets hypertension candidate from Phase Bio.

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

Dragonfly Takes Back IL-12 Immunotherapy From BMS

While the two biopharmas remain partnered on multiple Tri-Specific Natural Killer cell Engager Therapies (TriNKET) candidates from collaborations dating back to 2017, *Dragonfly Therapeutics, Inc.* revealed on 6 February that *Bristol Myers Squibb Company* will return all rights to DF6002, a Phase I anti-interleukin-12 candidate in dose-escalating studies as a monotherapy and as part of a combination regimen with BMS's Opdivo (nivolumab). The Waltham, MA-based firm said it will now accelerate the candidate's development across multiple indications and combination regimens.

BMS licensed the anti-IL-12 immunotherapy in August 2020 at undisclosed terms that included potential development, regulatory and commercial milestones worth up to $475m, as well as global sales royalties that could have reached as high as 24%. (Also see "*Bristol Licenses Dragonfly's IL-12 Program To Boost Immunotherapies*" - Scrip, 17 Aug, 2020.) Dragonfly did not say why BMS has decided to return rights to the asset, or what financial terms may be owed to its partner.

The Dragonfly/BMS relationship dates back to deals struck between Dragonfly and *Celgene Corporation* before the latter firm's acquisition by BMS in 2019. The original alliance centered on option rights for up to four immuno-oncology programs using the TriNKET technology. (Also see "*ACR Notebook: Lilly's Baricitinib Differentiates On Pain, Ironwood's Duzallo Progress, Corbus Nears Phase III*" - Scrip, 8 Nov, 2017.) Dragonfly noted that multiple TriNKET assets are currently part

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of BMS's clinical pipeline – these are Phase I/II BMS-986392 for solid tumors and Phase I CC-96191 and CC-92328, both for acute myelogenous leukemia.

During its Q4 2022 earnings call, BMS announced that executive VP, research and early development Rupert Vessey, a holdover from the Celgene transaction, will retire this coming July. (Also see "*BMS/Celgene Post-Merger Early R&D Strategy: Partnerships Are Still Key, Vessey Says*" - Scrip, 6 Feb, 2020.) CEO Giovani Caforio credited him with successfully integrating the Celgene pipeline into BMS's R&D apparatus.

Ji Xing Gets Global Rights To Hypertension Asset From PhaseBio

Ji Xing Pharmaceuticals obtained the global rights to PB6440, an oral selective aldosterone synthase inhibitor, on 6 February from *PhaseBio Pharmaceuticals, Inc.* for an undisclosed amount. PB6440 is currently under preclinical development for patients with treatment-resistant hypertension, according to PhaseBio. An investigational new drug (IND) filing for the molecule is expected in the first half of 2023.

Preclinical data suggest that PB6440 offers strong potency inhibiting aldosterone synthase, with very little impact on the biological functions of a homologous enzyme that is key to cortisol synthesis, Shanghai-based Ji Xing said.

Chong Kun Dang, Synaffix Ink $132m ADC Platform License Agreement

Chong Kun Dang Pharmaceutical Corp. reached an agreement with *Synaffix B.V.* on 6 February to license the latter's antibody-drug conjugate (ADC) platform technologies to advance development of next generation ADCs for cancer, in a deal worth up to $132m, including upfront and milestone payments, plus sales royalties. Chong Kun Dang has been collaborating with Synaffix on ADC development since 2019.

Under the deal, the South Korean firm gets the right to use Synaffix's three platform technologies GlycoConnect, which enables best-in-class therapeutic efficacy and tolerability, HydraSpace, which further differentiates efficacy and tolerability versus other site-specific ADC approaches, and toxSYN linker-payloads, which provide multiple options to maximize efficacy in light of tumor biology.

Karuna Picks Up TRPC4/5 Candidates From Defunct Goldfinch Bio

Following the 27 January announcement that it is ceasing operations due to financial challenges, *Goldfinch Bio, Inc.* licensed multiple investigational transient receptor potential canonical 4 and 5 (TRPC4/5) channel candidates to *Karuna Pharmaceuticals, Inc.*, on 2 February. Karuna obtains global development, manufacturing and commercialization rights to Goldfinch's lead clinical-stage candidate GFB-887 under the agreement.

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Karuna said it will evaluate the candidates as potential treatments for various psychiatric and neurological conditions, starting with GFB-887 for the treatment of mood and anxiety disorders. The biotech said it will share details of development plans for GFB-887 in H2 2023. Goldfinch suspended Phase II development of the TRPC5 ion channel inhibitor in focal segmental glomerulosclerosis and diabetic nephropathy in 2022.

Under the agreement, Goldfinch's assignment estate will get a $15m upfront payment and be eligible to realize up to $520m in milestone payments for each licensed candidate. Of that per-candidate amount, $410m is pegged to regulatory approval and commercial sales milestones, with Goldfinch also eligible for a single-digit royalty per product.

Purple Adds Trispecific Antibody Candidates Via Immunorizon Takeout

Purple Biotech Ltd. agreed on 2 February to acquire fellow Israeli firm *Immunorizon Ltd.*, giving the former an expanded portfolio of trispecific antibody candidates that target multiple antigens and offer the potential to address additional targets. Purple is to acquire all shares of Immunorizon in exchange for an upfront payment of $3.5m in cash and $3.5m in stock based on Immunorizon's average share price for the 60-day period preceding the deal's execution date.

Immunorizon shareholders can also realize development, regulatory and sales milestones up to $94m, along with single-digit sales royalties, although the accumulated payments, excluding the upfront fee, will not exceed $100m.

Founded in 2017, Immunorizon, previously known as ExploreBio1, develops conditionally activated, tumor-restricted T-and NK-cell engagers for cancer therapy. Its lead asset is a trispecific antibody that engages both T cells and NK cells to mount a localized immune response within the tumor microenvironment, the companies said.

Purple said the candidates it is acquiring differentiate from other multi-specific cell therapies targeting 5T4+ tumors due to its cleavable capping technology, which confines therapeutic activity to the local tumor microenvironment and potentially increases the anticipated therapeutic window in patients. Purple said it expects to file an investigational new drug (IND) within the next two years from Immunorizon's pipeline, in a parallel development program with its own programs.

Blue Water, AbVacc Team To Develop Monkeypox, Marburg Vaccines

Blue Water Vaccines, Inc. unveiled a collaboration on 1 February with *AbVacc, Inc.* for the joint development of vaccine candidates targeting monkeypox and Marburg virus disease. Both vaccine candidates will utilize Blue Water's norovirus shell and protrusion virus-like particle (VLP) platform, enabling the presentation of multiple antigens on the surface of either the S or P particle of a norovirus backbone.

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Blue Water said plans to explore a novel monkeypox candidate with AbVacc, an Integrated BioTherapeutics spinout, using this platform and conduct preclinical immunogenicity and efficacy studies. AbVacc, meanwhile, will utilize its expertise in Marburg virus to develop a novel vaccine candidate using Blue Water's VLP platform. The two companies will seek to identify Marburg antigens to be presented within BWV's VLP platform and optimize a potential vaccine candidate.

AbVacc noted that it is currently developing a monoclonal antibody for treatment the virus, IBT-T03, with discovery and preclinical development supported by multiple government grants. In May 2021, IBT obtained a $16.3m contract from the US *National Institute of Allergy and Infectious Diseases* to support manufacturing and a Phase I trial for the antibody.

Daewoong Licenses China Rights For IPF Candidate To CS Pharm

Daewoong Pharmaceutical Company Ltd. unveiled a licensing agreement with UK-headquartered CS Pharmaceuticals, on 31 January for a first-in-class prolyl-tRNA synthetase (PRF) inhibitor bersiporocin (DWN12088) in the Greater China region. CSP focuses on the development and commercialization of rare disease and ophthalmology products in China.

Under the agreement, CSP gets rights to develop bersiporocin for idiopathic pulmonary fibrosis (IPF) and potentially other fibrotic indications for a total consideration of up to $336m, including up to $76m in upfront and development milestone payments as well as double-digit royalties on net sales.

Bersiporocin is a first-in-class antifibrotic agent discovered by Daewoong. In 2022, Daewoong began a multi-regional Phase II clinical trial for IPF, supported by the Korea Drug Development Fund.

UniQure Licenses ALS Gene Therapy From Apic Bio

Gene therapy companies *uniQure N.V.* and *Apic Bio, Inc.* inked a licensing agreement on 31 January conferring global development and commercialization rights for Apic's APB-102, a one-time, intrathecally administered gene therapy intended to treat a rare form of amyotrophic lateral sclerosis (ALS) caused by mutations in superoxide dismutase 1 (SOD1) gene. Under the agreement, uniQure will pay $10m up front with Apic eligible to earn up to $45m in regulatory and sales milestones as well as tiered royalties on net sales.

The US Food and Drug Administration cleared an IND application for APB-102 in April 2021 and previously granted Orphan Drug (June 2019) and Fast Track (July 2021) designations. UniQure, which plans to initiate a Phase I/II trial of APB-102 in H2 2023, said the strengthens its pipeline of gene therapy candidate for neurological disorders and miRNA-based gene-silencing programs.

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In Brief:

- *Xencor, Inc.* and *Atreca, Inc.* announced on 6 February that they have selected the first program under their July 2020 collaboration on T-cell-engaging bispecific antibodies for cancer. (Also see "*Deal Watch: Merck's Busy Stretch Includes Collaborations With Dewpoint, Zymeworks*" - Scrip, 13 Jul, 2020.) The joint program starts with APN-346958, an Atreca-discovered antibody that targets a novel RNA-binding protein and is tumor-reactive in at least 50% of samples for six tumor types evaluated, the companies said. Those include colorectal, thyroid, head and neck, urothelial, melanoma and brain cancer. In preclinical studies, XmAb bispecific antibodies engineered by Xencor against APN-346958's demonstrated potent anti-tumor activity, the partners said. The firms plan to name a candidate this year with a goal of filing investigational new drug (IND) application by 2025.

- *Revive Therapeutics Ltd.* and *PharmaTher, Inc.* said on 3 February that they are collaborating on using the latter's microneedle patch technology as a potential delivery mechanism for MDMA (3,4-Methylenedioxy methamphetamine). Toronto-based Revive thinks MDMA could have therapeutic potential in depression, anxiety, abuse disorders and post-traumatic stress disorder.

- *Tonix Pharmaceuticals Holding Corp.* agreed on 2 February to acquire all assets of *Healion Bio, Inc.*, including its next-generation antiviral pipeline. Healion's drug portfolio includes a class of broad-spectrum, oral antiviral candidates with a novel host-directed mechanism of action. Host-directed antivirals modulate human cells and tissues, the companies explained, and are different from direct-acting antivirals, which inhibit virus proteins and processes.

- The UK's *Orbit Discovery Ltd.* said on 1 February that is partnering with *Endevica Bio* on a multi-target research collaboration to advance the latter's G-protein coupled receptor (GPCR)-targeted therapeutics for cancer cachexia. Endevica will option rights to the peptide hits resulting from Orbit's screening efforts to identify the agonism of proteins.

- France's *Sensorion S.A.* announced on 31 January a collaboration with medical device maker *Eveon* to design, develop and optimize devices that will deliver the former's gene therapy candidates to the inner ear. Sensorion said this effort includes development of a device for OTOF-GT, a gene therapy partnered with *Institut Pasteur* targeting hereditary, monogenic deafness caused by mutations of the gene encoding for otoferlin.

- *Roche Holding AG* subsidiary *Spark Therapeutics, Inc.* revealed on 27 January that it is partnering with Neurochase on delivery mechanisms for Spark's gene therapy candidates for central nervous system disorders. Based in Cardiff, Wales, Neurochase said it aims to improve targeted delivery of AAV gene therapies to neural structures using a method of convection enhanced delivery.

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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 "*UK Biotechs Still Set On Cashing Out*" - Scrip, 6 Feb, 2023.)	Excluding the multinational majors AstraZeneca and GSK, the UK has yet to produce a truly successful scaled pharma company, despite having boasted several innovative start-ups. Whether that represents a negative, however, is a matter for debate.
(Also see "*Advanz Agrees Multi-Market Omalizumab Deal With Alvotech*" - Generics Bulletin, 6 Feb, 2023.)	Advanz and Alvotech have struck a deal that will give Advanz exclusive rights to the biosimilars developer's Xolair (omalizumab) rival in multiple markets around the world.
(Also see "*Behind A Rekindled Dream And China Biotech's New Reality*" - Scrip, 2 Feb, 2023.)	The latest mega deals aimed at bringing Chinese innovation to the US have rekindled go-global hopes for a sector badly needing some cheer. But some investors say out-licensing may be the best route and that Chinese biotech must scale back its do-all mentality and focus on what it does best amid a new reality.
(Also see "*Takeda On Continued Lookout For Assets After Recent Deals*" - Scrip, 2 Feb, 2023.)	Takeda reports solid growth in its fiscal nine months as it hints more may be to come after recent major deals to expand the mid- to late-stage pipeline and highlights progress for some key internal assets.
(Also see "*Fresenius Kabi And Formycon Ally On Stelara Rival*" - Generics Bulletin, 2 Feb, 2023.)	Fresenius Kabi and Formycon have announced a global licensing deal for the FYB202 ustekinumabproposed biosimilar rival to Stelara. The deal comes as Formycon has revealed plans to raise further funds to funnel into research and development through a fresh share issue.
(Also see "*HK inno.N Eyes 2025 Korea Opportunity With mAbxience Denosumab Deal*" - Generics Bulletin, 31 Jan, 2023.)	Ahead of wrapping up a Phase III clinical trial for its proposed biosimilar denosumab candidate later this year, mAbxience has out-licensed marketing rights in Korea to local player HK inno.N, with a patent expiry opportunity in 2025.

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