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Bolstering IPF 'Bridge,' Boehringer signs potential €1.1 billion ATX inhibitor deal

By Randy Osborne, Staff Writer

Seongnam, Korea-based Bridge Biotherapeutics Inc. nailed down a deal with Boehringer Ingelheim GmbH (BI) to develop the former's phase I autotaxin (ATX) inhibitor, BBT-877, for fibrosing interstitial lung diseases, including idiopathic pulmonary fibrosis (IPF).

BI, of Ingelheim, Germany, is providing up-front and near-term payments of €45 million (US$50.4 million) and Bridge could collect more than €1.1 billion in additional payments if development,

See Bridge, page 3

Pharma investors return for Medicxi's $449M third fund

By Nuala Moran, Staff Writer

LONDON –Medicxi has closed a €400 million (US$449 million) third fund, bringing the amount raised by the venture capital firm since it split off from its parent Index Ventures three years ago, to more than $1 billion.

The Medicxi fund III was closed in just six weeks. "It was so fast, exactly because of how much more interest there is in biotech in Europe. It has become a much more mainstream asset class," said Francesco De Rubertis, co-founder and partner at the firm.

Whereas a few years ago, only around 10% of European fund managers invested in biotech, around 60% to 70% do so now. Having set out to raise between €250 million and €400 million, London-based Medicxi had offers of €1 billion. "I'm not saying any VC fund would have an easy ride; we are at the top of the group. Raising fund III was fast because existing LPs know us very well," De Rubertis told *BioWorld*.

Novartis AG and Johnson &

See Medicxi, page 4

Kronos makes time for series A financing, adds $105M with help from execs, board members

By Lee Landenberger, Staff Writer

Kronos Bio Inc. closed a $105 million series A preferred stock financing, shored up by a board composed of longtime pharma executives that includes the company CEO and president, Norbert Bischofberger, the former Gilead Sciences Inc.

See Kronos, page 5

Singapore startup Aum bags triple-action cancer candidate in agreement with Inflection

By Elise Mak, Staff writer

HONG KONG – Singaporean biotech company Aum Biosciences Pte. Ltd. has in-licensed a potentially first-in-class PIM/PI3K/mTOR inhibitor from Inflection Biosciences Ltd., of Dublin and London, to develop it globally to treat a wide range of cancers.

See Aum, page 6

The fix isn't in yet, as prices, politics and pay-fors prolong passage of Rx remedy

By Mari Serebrov, Regulatory Editor

The best way to score political points is to actually do something about U.S. prescription drug prices.

That's the message members of the New Democrat Coalition Health Care Task Force delivered Wednesday to their party leadership in the House, as they requested another vote next week on a package of bipartisan drug pricing bills – this time minus the partisan provisions that Democrats knew would never fly in a Republican-controlled Senate.

"The rising cost of prescription drugs remains of paramount concern to all members, irrespective of political affiliation. There are families in every single congressional district struggling to pay for their prescription drugs. As such, this challenge calls for a unified approach," the task force said in a letter to Rep. Nancy Pelosi (D-Calif.) and other House Democratic leaders.

See Legislation, page 7

CD47 race heats up in China as I-Mab's antibody cleared for trials in advanced tumors

By Elise Mak, Staff Writer

HONG KONG – China has approved the fourth homegrown CD47 antibody to start clinical trials, intensifying the local CD47 race. Chinese biologics developer I-Mab Biopharma (Shanghai) Co. Ltd. said it received the go-ahead for the clinical

See I-Mab, page 8

Market uncertainty fails to slow biopharma IPO activity

By Peter Winter, BioWorld Insight Editor

Despite the ups and downs of the general markets and a U.S. government shutdown at the beginning of the year that contributed to no biopharma companies graduating to the public ranks in January, the enthusiasm for biopharma IPOs has remained steady since then. In fact, a flurry of IPO listings on U.S. stock exchanges last month

See IPOs, page 9

Other news to note

Apellis Pharmaceuticals Inc., of Crestwood, Ky., said it plans to develop APL-9 for the prevention of complement immune system activation coincident with adeno-associated virus vector administration for gene therapies. APL-9 is a pegylated synthetic cyclic peptide designed to modulate the complement cascade centrally at C3.

Arvinas Inc., of New Haven, Conn., reported preclinical data on its tau-targeted Protac protein degrader program at the Alzheimer's Association International Conference in Los Angeles. After parenteral administration of the drug, more than 95% of pathologic tau protein was eliminated in the brain of a mouse tauopathy model.

Bausch Health Companies Inc., of Bridgewater, N.J. said the U.S. District Court of New Jersey upheld the validity of a patent protecting Relistor (methylnaltrexone bromide) that expires in March 2031 and ruled that Actavis Laboratories FL Inc., a subsidiary of Jerusalem-based **Teva Pharmaceutical Industries Ltd.**, infringed on the patent.

Bayer Healthcare Pharmaceuticals Inc., of Whippany, N.J., **Bristol-Myers Squibb Co.**, of New York, and **Ono Pharmaceutical Co. Ltd.**, of Osaka, Japan, are collaborating to test Bayer's kinase inhibitor, Stivarga (regorafenib), and Bristol-Myers Squibb and Ono's anti-PD-1 immune checkpoint inhibitor, Opdivo (nivolumab), in patients with micro-satellite stable metastatic colorectal cancer. Terms of the collaboration weren't disclosed.

Bolder Biotechnology Inc., of Boulder, Colo., said it was awarded a $593,507 two-year Small Business Innovation Research grant from the National Institute of Allergy and Infectious Diseases of the NIH. It will fund a joint research project between the company and Indiana University School of Medicine to understand the ability of combinations of the company's recombinant hematopoietic growth factors to improve survival when administered as late as 48 hours following lethal radiation exposure, a time when other therapies are ineffective. Receipt of the entire grant award is contingent upon the achievement of certain research milestones.

Burst Biologics, of Boise, Idaho, said it published a research study in *Regenerative Medicine* that focuses on a comprehensive overview of the quality attributes, clinical suitability and efficacy of an umbilical cord blood (UCB)-sourced allograft. Previous research has demonstrated that UCB contains cytokines and growth factors, components that are integral to bone consolidation and tissue repair. The research identifies a unique liaison among UCB-sourced allograft, host mesenchymal stem cells and their secreted exosomes that influences tissue regeneration in vivo. Exosomes from mesenchymal stem cells treated with a UCB-sourced allograft also demonstrated boosted potential for tissue regeneration.

Emmaus Life Sciences Inc., of Torrance, Calif., and **Mynd Analytics Inc.**, said they completed the merger transaction, following stockholder approval by both companies. Mynd Analytics, which traded on Nasdaq under the ticker symbol MYND, changed its name to Emmaus Life Sciences Inc., while the privately owned Emmaus changed its name to EMI Inc., becoming a wholly owned operating subsidiary of Emmaus Life Sciences Inc., with its shares trading on Nasdaq under the ticker symbol EMMA. As part of the merger, the former stockholders of Emmaus will receive approximately 1.05 shares of Mynd common stock for each share of common stock held prior to the merger. That exchange ratio takes into account a 1-for-6 reverse stock split of the Mynd shares, also effected prior to the merger.

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Bridge

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regulatory and commercial milestones are achieved, plus staggered royalties into the double digits. BBT-877 is due to enter phase II trials within the next 12 months.

The pair will first take aim with BBT-877 at IPF, already of interest for BI with its marketed antifibrotic tyrosine kinase inhibitor, Ofev (nintedanib), which slows disease progression by reducing the decline in lung function. It's approved for IPF in more than 70 countries, including the U.S., the EU and Japan.

By blocking the ATX enzyme, BBT-877 attacks a key mediator of fibrosis, and preclinical models have turned up promising safety and efficacy, with the potential for combining with existing therapies, the companies said.

BI has been busy in Korea lately. Earlier this month, the firm tapped that country's largest pharmaceutical company, Yuhan Corp., for a collaboration and license agreement to develop a first-in-class dual agonist to treat nonalcoholic steatohepatitis and related liver disease. The firms are combining the activities of long-acting glucagon-like peptide-1 with fibroblast growth factor 21 in a single molecule. Yuhan collected up-front and near-term payments of $40 million and could bank as much as $830 million more if prespecified goals are reached, plus tiered royalties on future net sales. (See *BioWorld*, July 2, 2019.)

IPF has been grabbing headlines, too. The indication is targeted by Galapagos NV's oral ATX inhibitor, GLPG-1690, undergoing a phase III trial. It's the most advanced asset in Foster City, Calif.-based Gilead Sciences Inc.'s just-expanded partnership with Galapagos, of Mechelen, Belgium, other than already-partnered filgotinib. This week, the duo signed a 10-year R&D alliance under which Galapagos adds $3.95 billion up front in cash plus another $1.1 billion in equity, in return for which Gilead will have an option to ex-European rights on six clinical-stage programs and another 20 in preclinical research. (See *BioWorld*, July 16, 2019.)

Rare, debilitating and fatal, IPF affects about 3 million people worldwide, and the Pulmonary Fibrosis Foundation notes that current treatments include medications, oxygen therapy, non-medical treatments such as exercise, and even lung transplant. Trying another approach is Genkyotex SA, of Paris, which said the FDA has approved the IND allowing for the start of a phase II trial with GTK-831, an inhibitor of NADPH oxidase 1 (NOX1) and NOX4. Earlier this year, the compound missed its primary endpoint in a phase II study testing it against primary biliary cholangitis. (See *BioWorld*, May 3, 2019.) ♦

Other news to note

Immunocore Ltd., of Oxford, U.K., and Pulse Infoframe Inc., a data aggregation and analytics company, said they plan to support the first global patient registry in uveal melanoma. The registry will include institutions from across the U.S., U.K. and Australia, with enrollment into the registry expected to begin next month. The goal of the resource is to create a benchmark framework, or ecosystem, for collecting and assessing clinical outcomes, as well as providing necessary data for future genetic, subphenotype and biomarker research.

Kinarx LLC, of West Lafayette, Ind., a Purdue University-affiliated startup, has licensed through the Purdue Research Foundation Office of Technology Commercialization a series of drug compounds that have shown promise in treating patients who have a recurrence of acute myeloid leukemia (AML). Researchers in Herman Sintim's lab have developed a series of new compounds that inhibit mutant FLT3 kinases. In mice models of drug-resistant AML, the compounds performed better than gilteritinib and quizartinib. The company is also working on a treatment for a type of lung cancer with mutation in the RET kinase, which is found in about 2% of patients.

Macrogenics Inc., of Rockville, Md., said its collaboration and license agreement with **Les Laboratoires Servier SAS**, of Suresnes, France, will be terminated by Jan. 15, 2020, or sooner if agreed to by the parties. The companies entered their agreement in September 2012 to develop and commercialize flotetuzumab and other earlier-stage Dual-Affinity Re-Targeting, or DART, molecules, in all regions other than North America, Japan, South Korea and India. Servier recently served notice of its intention to terminate the agreement and Macrogenics will now regain full global rights to develop and commercialize flotetuzumab. (See *BioWorld*, Sept,20, 2012.)

Merck KGaA, of Darmstadt, Germany, and the Broad Institute of MIT and Harvard University, reported they have signed an agreement to offer nonexclusive licenses to CRISPR intellectual property (IP) under their respective control for use in commercial research and product development. Under the agreement, companies applying CRISPR in their research and development activities can license both sets of IP through the Broad Institute. The framework is designed to allow other key patent holders to participate in the future, either through this framework or via a third-party patent pool or collaboration, to further streamline nonexclusive access to key CRISPR technology.

Neurogene Inc., of New York, said it has enrolled the first patient in a natural history study of Charcot-Marie-Tooth disease, type 4 (CMT4J), a rare inherited peripheral neuropathy. Approximately 20 patients with genetically confirmed CMT4J will be enrolled. It is being conducted under a collaboration between Neurogene and UT Southwestern Medical Center as one of multiple sponsored research agreements. The goal is to provide data to support a future gene therapy clinical trial.

Precision Biosciences Inc., of Durham, N.C., said it opened a manufacturing center for advanced therapeutics. The current good manufacturing process-compliant facility will be dedicated to genome-edited, off-the-shelf CAR T-cell therapy products.

Samumed LLC, of San Diego, said preclinical data published in *Aging Cell* demonstrated that SM-07883, a small-molecule dual-specificity tyrosine phosphorylation-regulated kinase 1A inhibitor, inhibits tau pathology and associated neuroinflammation, both of which are implicated in Alzheimer's disease. SM-07883 is in phase I testing.

Medicxi

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Johnson Innovation returned as cornerstone pharma investors, along with all the institutional investors that backed Medicxi's two earlier funds. New investors include hospital foundations and medical institutions.

Fund III will be steered by Medicxi's scientific advisory board, which includes scientific and commercial expertise of executives from Novartis, Johnson & Johnson, Glaxosmithkline plc and the Google health VC fund Verily.

The life sciences team of Index spun out in February 2016, taking with them all the existing life sciences portfolio companies and arriving on the scene fully fledged, with the $250 million Medicxi I fund. That was backed by the corporate venture arms of GSK and Johnson & Johnson. (See *BioWorld*, Feb. 2, 2016.)

The $300 million second fund, which launched in 2017, attracted Novartis and Verily as cornerstone investors. (See *BioWorld*, June 15, 2017.)

Both Medicxi's first fund, specializing in early stage assets, and the second, which is interested in programs post-phase II, will be fully invested by the end of 2019. "The follow-on to both would have been at the same time, so we decided to do one, not two fundraisings," De Rubertis said.

As a result, fund III will invest across the board, from discovery to late-stage clinical assets. Whilst maintaining its asset-focused model of investing in programs and not the formation of startups, Medicxi III will be making investments in more mature companies with underlying platform technologies and/or a number of assets.

De Rubertis is particularly keen on doing more deals like those struck recently with two of Europe's leading drug discovery specialists, Sosei Heptares and Evotec SE.

In February, Medicxi announced funding commitments of up to $45.8 million to set up two single-asset companies, Orexia Ltd. and Inexia Ltd., around orexin agonists that Sosei Heptares discovered using its G protein-coupled receptor technologies. Preclinical work to advance the two programs, in the treatment of narcolepsy, is being outsourced from the Medicxi-backed startups to Sosei Heptares. (See *BioWorld*, Feb. 6, 2019.)

> *"I want the message to get out to drug hunters, that there is capital and expertise to advance their projects.*
>
> Francesco De Rubertis
> Co-founder/Partner, Medicxi Ventures

Similarly, Medicxi led the investment of $33.6 million into Evotec spinout Breakpoint Therapeutics GmbH, announced earlier this month. The new "virtual" company has taken on a number of discovery-stage projects initiated by Evotec in the field of DNA damage response. While a separate legal entity, Breakpoint is based within Evotec and will contract out all future preclinical research to its parent. (See *BioWorld*, July 9, 2019.)

"These are the kind of deals we really love; to get good companies with good assets to use our cash," De Rubertis said.

Medicxi is open to making investments in the U.S. from fund III, but given its connections, expects most to be in European companies.

De Rubertis also would like to make academics aware that there is funding to prime commercialization of their research. "I remember when I was a scientist, the platform was not available. I want the message to get out to drug hunters, that there is capital and expertise to advance their projects," he said. ♦

Other news to note

Silence Therapeutics plc, of London, and **Mallinckrodt plc**, of Staines-upon-Thames, U.K., said they entered a collaboration that will allow the development and commercialization of RNAi drug targets designed to inhibit or "silence" the complement cascade, a group of proteins that are involved in the immune system and that play a role in the development of inflammation. Those proteins are known to contribute to the pathogenesis of many diseases, including autoimmune diseases. Under the terms of the agreement, Mallinckrodt will obtain an exclusive worldwide license to Silence's C3 complement asset, SLN-500, with options to license up to two additional complement-targeted assets in Silence's preclinical complement-directed RNAi development program. Silence will be responsible for preclinical activities, and for executing the development program of each asset until the end of phase I, after which Mallinckrodt will assume clinical development and responsibility for global commercialization. Mallinckrodt has agreed to provide an up-front payment of $20 million. Silence is also eligible to receive up to $10 million in research milestones for SLN-500 and for each optioned asset, in addition to funding for phase I development including GMP manufacturing. Other potential added clinical and regulatory milestone payments of up to $100 million for SLN-500 will be available, as well as commercial milestone payments of up to $563 million. Separately, Mallinckrodt announced that, acting through a subsidiary company, it has agreed to make an equity investment of $5 million in Silence.

Sosei Group Corp., of Tokyo, said partner **Formosa Pharmaceuticals Inc.**, of Taipei, Taiwan, received FDA approval for an IND to start trials of APP-13007 in postoperative inflammation of the eye, triggering a $2.5 million milestone payment to Sosei Heptares.

Kronos

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R&D executive vice president and chief science officer.

Bischofberger joined Kronos in May 2018 after having been at Gilead for more than 30 years.

Other Kronos' board members who pitched in include chair Arie Belldegrun, founder of Kite Pharma Inc. and co-founder of Allogene Therapeutics Inc. and Vida Ventures, along with John Martin, former Gilead chairman and CEO.

Norbert Bischofberger, CEO and president, Kronos Bio

"I knew of Arie but had never met him personally," Bischofberger told *BioWorld*. "When I was at Gilead, we acquired Kite, so in that six- to eight-month dance I got to know him. And at that point I was thinking about doing something with a smaller company. I thought, 'I'm still young. I want to do it again,' and Arie said, 'Why don't you come to Kronos.' Then John Martin said, 'Whatever you do, I'm coming with you.'"

Teamwise, Bischofberger added, it's going well and moneywise it's just fine for the startup founded in 2017. "To finance everything through 2021, the next two years, we need $50 million, so we have a nice runway," he said.

The financing was led by Vida Ventures LLC and Omega Funds, with participation from Nextech, GV, Perceptive Advisors, Invus and Polaris Partners.

The Kronos platform, the Small Molecule Microarray (SMM), stands on more than a decade of research by its founder, Angela Koehler, associate professor of biological engineering at MIT. The platform is designed to discover modulators or degraders of historically undruggable targets, such as transcription factors. The platform can identify compounds to bind to target proteins directly or interfere at nanomolar potency with protein activity. SMM enables discovery of hits that act through a variety of mechanisms, including disruption of protein-protein or protein-DNA interactions, or indirect modulation of target protein activity by binding to co-factors or other protein complex members. The goal is to find binding pockets in proteins that are considered to be undruggable.

Bischofberger said the platform can target the undruggable proteins in a context that allows it to identify the proper active, small molecules. He said transcription factors never exist in isolation, they're always complex, sometimes up to a dozen of them, and there is DNA involved adding to the complexity.

"We screen not against isolated proteins, like we did at Gilead, but we screen for cell extracts," he said. "You want inhibitors to exist in complex ways with other proteins and you don't take the transcription factor out of its native environment. That's what I like about this technology. It allows you to find that screen."

The San Mateo, Calif., and Cambridge, Mass.- based firm plans to staff up in the coming year using the series A money.

"We have two advanced programs now. We're in the lead optimization stage and we're moving into animal studies then clinical development," Bischofberger said. "We'll need a chief medical officer and a project manager. All of that will be in San Mateo, so we're thinking of maybe next year adding 10 to 15 people. At the moment, there are 12 [full-time employees] in Cambridge, the site of discovery, so we're going to double that."

Kronos also has contracted 25 chemists in India and China helping on its four programs. In the discovery phase are programs on transcription factors and oncoproteins and on finding novel E3 ligases. The preclinical programs are MYC/androgen receptor related cofactor research and a cyclin-dependent kinase 9 study.

"My goal and ambition is to repeat the Gilead thing one more time," Bischofberger said. "I want to have a commercial company."

With that goal comes constant fundraising, ultimately a series B and beyond.

"I do hope we can grow out of that. There will be more fundraising fairly soon," he said. "At Gilead, it took 10 years – from the founding it was 14 years – until we became permanently profitable, where you don't depend on having to be raising money. If you have the right compound and you pick the right indication, you can get approval fairly quickly. I want to become profitable." ♦

Financings

Amarin Corp. plc, of Dublin, plans to sell $400 million of its American depository shares (ADSs) in a public offering. The proceeds will be used to support the launch of Vascepa (icosapent ethyl) in an expanded indication based on the Reduce-It study, which is under review by the FDA. The capital will also be used for increasing the commercial supply of Vascepa from third-party suppliers and for general corporate purposes. The underwriters have a 30-day option to purchase up to an additional $60 million of ADSs. J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, Jefferies LLC and Cantor Fitzgerald & Co. are acting as the joint book-running managers in the offering. Amarin's ADSs (NASDAQ:AMRN) closed down $2.17, or 10.3%, to $18.90 on Thursday.

Aqilion AB, of Helsingborg, Sweden, raised SEK100 million ($10.7 million) through the conversion of outstanding warrants issued as part of an offering in March 2018.

Azurrx Biopharma Inc., of Brooklyn, N.Y., priced a public offering of 5 million shares at $1 per share, which is expected to close on or about July 22. The underwriters have a 30-day option to purchase up to 750,000 additional shares. The company plans to use the capital for development of MS-1819-SD for exocrine pancreatic insufficiency, its preclinical programs for AZX-1103, and for other general corporate purposes and capital expenditures. H.C. Wainwright & Co. is acting as the sole book-running manager, while National Securities Corp. is acting as a co-manager for the offering. Shares of Azurrx (NASDAQ:AZRX) closed down 10.4 cents, or 9.9%, to 94.7 cents on Thursday.

Aum

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Under the agreement, Aum obtains the exclusive worldwide rights to develop, manufacture and commercialize Inflection's IBL-302, which will be renamed AUM-302 under its pipeline. Without revealing the financial terms, Aum CEO Vishal Doshi told *BioWorld* that Inflection will receive an up-front payment, future milestone payments and royalties on future sales.

Vishal Doshi, CEO, Aum

"IND-enabling studies will be initiated in 2020. Once this regulatory work is completed, we plan to conduct our first patient studies at sites in Singapore, Korea, Taiwan and possibly Australia," said Doshi.

Aum will lend its experience in planning and executing global clinical trial programs while Inflection contributes with its understanding of AUM-302.

What makes AUM-302 unique is the multiple targets that it interacts with in the cell signaling pathway, Doshi explained. "AUM-302 is a multikinase inhibitor, leading to inhibition of three very important cancer signaling pathways, namely PI3K, mTOR and PIM."

He added that there are a number of PI3K inhibitors on the market and in development. However, the cancer cells soon develop resistance to the therapy, which is initially potent, primarily by recruiting other cell signaling pathways that they up-regulate.

"A key resistance pathway involves PIM, which AUM-302 also inhibits, making it a very exciting product to evaluate in tumor types prone to developing resistance to treatment," added Doshi.

Currently in preclinical testing, AUM-302 has been evaluated in more than 700 cancer cell lines and researchers believe it can be developed against multiple cancer types, including breast cancer, lung cancer, leukemia and neuroblastoma.

Asia first

The Asia market is a priority of Singapore-based Aum. It adopts the "Asia to global" approach to bring crucial drugs to Asian patients as quickly as possible, before introducing them to those in need globally.

Indeed, the most common types of cancers in Asia are lung cancer for men and breast cancer for women. In Asia, a continent that represents roughly 60% of the world population and half the global burden of cancer, new cancer cases are estimated to reach 14 million by 2030.

The "Asia-first" drugmaker is very young, yet ambitious. Established in March 2018, Aum has raised S$2.04 million (US$1.5 million) in a seed funding round to develop affordable cancer therapies in Asia.

Aum vows to pioneer a shift in the traditional "West to East" model, which it says deprioritizes the Asian market for drug development in favor of the U.S. and European markets and relies on a "Western" pricing structure that places the medicine out of the reach of many who need it.

For now, Aum is focused on small-molecule drugs that are easier and cheaper to produce compared to biologics. Through acquiring new high-potential candidates from academia and industry partners, Aum is developing a pipeline of best-in-class and first-in-class small-molecule inhibitors that demonstrate potential efficacy and lower toxicity to facilitate intrapipeline combinatorial strategies. It stresses synergies between assets to create an appealing overall portfolio value.

Aum focuses on combination therapy as a "hallmark of cancer treatment." As a disease can spread beyond its original site and become resistant to some drugs, there is a need for multiple approaches to attack it. AUM-302 fits the bill, as does its first asset, AUM-001. The highly selective Mnk inhibitor acquired from Singapore's Agency for Science, Technology and Research targets solid tumors and hematological malignancies as a monotherapy, in combination with standard of care, or as an immuno-oncology combination therapy.

AUM-302 could also be more than just a monotherapy, as it has shown combination potential. It could address the major problem of patient resistance to certain drugs.

"There is a high likelihood that AUM-302 and AUM-001 may make a very potent combination therapy," Doshi said.

"AUM-001 has a very favorable safety profile lending itself well to combination therapy, and its mode of action in combination with a PI3K/mTOR/PIM inhibitor would leave few oncogenic drug-resistant pathways for tumor cells to recruit."

Currently, Aum has only made public two assets in its pipeline, which is still growing. "We will continue to build out our pipeline of novel small-molecule cancer therapies, always keeping in mind how they could be combined in future chemotherapy regimens," Doshi added. ♦

Financings

Delcath Systems Inc., of New York, closed a previously announced private placement with gross proceeds of $20 million at a combined price of $1,000 per unit. Each unit consists of one preferred share initially convertible into 16,667 shares of common stock at an initial conversion price of 6 cents per share and a common stock purchase warrant. After expenses, Delcath received net proceeds of approximately $18.35 million, which the company will use to complete enrollment of its registration Focus study testing melphalan/HDS in ocular melanoma liver metastases. Roth Capital Partners acted as the sole placement agent for the offering.

Forty Seven Inc., of Menlo Park, Calif., priced a public offering of 9.4 million shares at $8 per share, grossing the company $75 million. The underwriters have a 30-day option to purchase up to 1.4 million additional shares. Morgan Stanley & Co. LLC and Credit Suisse Securities LLC are acting as joint book-running managers, Guggenheim Securities LLC and Canaccord Genuity LLC are acting as lead managers, and H.C. Wainwright & Co. LLC and Roth Capital Partners LLC are acting as co-managers for the offering. Shares of Forty Seven (NASDAQ:FTSV) closed down 1 cent at $8.75 on Thursday.

Legislation

Continued from page 1

Ignoring the objection of Republican members, House leadership in May bundled three bipartisan bills aimed at drug competition – the BLOCKING Act, CREATES Act and the Protecting Consumer Access to Generic Drugs Act – with definitively partisan measures intended to reinvigorate the exchange provisions of the Affordable Care Act (ACA) into H.R. 987.

The idea was to use the $4 billion in savings the drug pricing bills are expected to generate over the next decade to offset the cost of the ACA fix. As a result, H.R. 987 passed the House on pretty much a party-line vote and has little chance of a vote in the Senate. (See *BioWorld*, May 16, 2019.)

Bringing the bipartisan measures to the House floor in a standalone bill would "reiterate our commitment to tackling the rising cost of prescription drugs in a bipartisan manner before the August recess," according to the letter, which was signed by the co-chairs of the task force, Reps. Kurt Schrader (Ore.), Kim Schrier (Wash.), Angie Craig (Minn.) and Greg Stanton (Ariz.), along with eight other members.

During the recess, House members, who are all up for re-election next year unless they're retiring, will be facing constituents clamoring for action rather than rhetoric. While a second vote on H.R. 987 would give House members talking points on their efforts to tackle drug prices, it likely would make little difference in the Senate, which is crafting its own comprehensive package aimed at lowering the cost of health care. That package includes versions of the bipartisan provisions in H.R. 987.

Delayed action

Senate leaders had planned to hold a vote on the package – which will consist of bipartisan bills passed by the Finance, Judiciary, and Health Education, Labor and Pensions (HELP) Committees – before the recess, but the Finance Committee has yet to complete its part of the legislation.

The Finance bill is being hammered out by committee Chair Chuck Grassley (R-Iowa) and Ranking Member Ron Wyden (D-Ore.). The holdup appears to be a delay in getting a formal estimate from the Congressional Budget Office on the economic impact of the proposals in the bill.

Although the bill has yet to be publicly disclosed, it reportedly includes a provision to limit out-of-pocket (OOP) drug costs for Medicare beneficiaries. One concern is that the trade-off for an OOP cap would mean a bigger tab for the government or higher premiums for all Medicare beneficiaries.

The threat of higher premiums is what killed an administration rule last week that would have required Medicare plans to pass drug rebates to beneficiaries at the point of sale. While the rule would have helped those beneficiaries struggling to pay their OOP pharmacy costs, it could have resulted in higher premiums for all beneficiaries, because the rebates drug companies pay pharmacy benefit managers for formulary placement are generally used to hold down those premiums. (See *BioWorld*, July 12, 2019.)

> *"The rising cost of prescription drugs remains of paramount concern to all members, irrespective of political affiliation.*
>
> New Democrat Coalition Health Care Task Force
> U.S. House of Representatives

Once the Finance Committee has the CBO estimate, it will have to vote on the bill to advance it to the full Senate. The Judiciary and the HELP Committees sent their part of the package to the Senate floor late last month. (See *BioWorld*, June 27, 2019, and June 28, 2019.)

HELP's Lower Health Care Costs Act is itself a multi-tentacled package consisting of 54 proposals, including the CREATES Act, which creates a legal path for sponsors to get the samples of the reference drug needed to develop a generic or biosimilar, and the BLOCKING Act, which is intended to keep drug companies from "parking" the 180-day first generic exclusivity in an attempt to delay competition.

The Judiciary piece includes three bills intended to stop anticompetitive shenanigans and one that charges the Federal Trade Commission with studying the role of supply chain middlemen to determine whether they're the good guys or the bad guys when it comes to drug prices.

As the Senate waits to assemble its health care package, the House continues to move on other measures aimed at drug prices. Wednesday, the House Energy and Commerce Committee voted to send H.R. 2296 to the House floor with a new name, the More Efficient Tools to Realize Information for Consumers (METRIC) Act.

Previously known as the FAIR Drug Pricing Act, the METRIC Act is a compilation of bipartisan transparency measures intended to disclose how drug prices are set and what role the supply chain plays in pricing. One of the provisions would require drug companies to notify Health and Human Services at least 30 days in advance of certain price increases and submit a detailed report justifying the increase. (See *BioWorld*, July 12, 2019.) ♦

Financings

Fulcrum Therapeutics Inc., of Cambridge, Mass., sold 4.5 million shares at $16 per share in an IPO, grossing the company $72 million that Fulcrum plans to use to support the development of its p38 kinase inhibitor, losmapimod, for facioscapulohumeral muscular dystrophy and for its hemoglobinopathies program. The underwriters have a 30-day option to purchase up to 675,000 additional shares. Morgan Stanley, BofA Merrill Lynch and SVB Leerink are acting as joint book-running managers for the offering. Shares of Fulcrum (NASDAQ:FULC) closed down $2.50, or 15.6%, to $13.50 after its first day of trading on Thursday.

I-Mab

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study of TJC-4, its differentiated fully human CD47 monoclonal antibody for treating advanced malignant tumors.

This is the second IND approval for TJC-4; the first came from the U.S. FDA in January. Weimin Tang, executive vice president of global business development at I-Mab, told *BioWorld* that dosing of the first patient cohort at 1 mg/kg has been completed and no major hematological safety concerns have been identified so far.

"In China, we have just received the approval for initiating clinical trials. We plan to explore multiple indications by either monotherapy or combination therapies in patients with hematological or solid tumors," he said.

"We are developing our proprietary CD47 antibody, TJC-4, rapidly in the U.S. and China. Our strategy is to simultaneously develop TJC-4 globally for maximal efficiency and early commercialization."

Calling TJC-4 "a potential global best-in-class" CD47 antibody, Tang said it is "designed to avoid inherent hematologic toxicity commonly found in this class of drug candidates. The key differentiation of TJC-4 stems from its unique property to interact with a rare epitope selected from initial antibody screen. TJC-4 binds minimally to red blood cells while maintaining high tumor-killing property.

"TJC-4 does not cause hematologic toxicity in nonhuman primates," he added.

CD47 has emerged as another key target in the immuno-oncology field, following the much-studied PD-1 and PD-L1 receptors. CD47 is dubbed as the "don't eat me" protein, and it binds to the SIRP-alpha receptor on macrophages. The idea is that by blocking the CD47-SIRP-alpha signaling pathway, the "don't eat me" signal will be switched off and macrophages will then swallow the tumor cells.

CD47 race at home and abroad

So far, there are no approved anti-CD47 therapies globally.

But at least six Chinese biotech companies are known to be developing CD47 antibodies, with four in clinical stages already, including I-Mab's TJC-4. The Chinese regulators are granting IND approvals faster to intensify the race.

In June 2018, Chinese biotech giant Jiangsu Hengrui Medicine Co. Ltd. had its SHR-1603 approved for clinical trials in China, making it the first domestic player to obtain the approval. But the phase I study was withheld. Tang suggested the delay was "likely because of the hematologic adverse events."

Three months later, Innovent Biologics Inc., of Suzhou, China, received an IND greenlight for its IBI-188. It plans to launch several clinical trials to explore IBI-188's potential in treating multiple tumor types, including non-Hodgkin lymphoma and ovarian cancer. (See *BioWorld*, Sept. 13, 2018.)

In May, Shanghai-based Immuneonco Biopharmaceuticals (Shanghai) Co. Ltd. said its drug candidate, IMM-01, was granted IND approval in China to investigate its efficacy for leukemia. It took the company only 39 working days to receive that approval.

Outside of China, other players advancing CD47-targeting drugs include Canadian firm Trillium Therapeutics Inc., the aptly named Forty Seven Inc., of Menlo Park, Calif., and biopharma powerhouse Celgene Corp. (See *BioWorld*, May 8, 2018.)

Of all the CD47 antibodies under development, only Forty Seven's Hu5F9 is in phase II testing; the others are still in phase I.

Since China now accepts overseas clinical data, companies that have already started clinical trials in the U.S. may benefit from that policy to speed up their development programs in China. Innovent, which conducts clinical trials on IBI-188 at home and abroad simultaneously, plans to do so.

Two more Chinese players are also known to be studying CD47-targeting therapies. Tasly Biopharmaceuticals Co. Ltd. has SY-102 for leukemia and solid tumors in the preclinical stage, as revealed in its prospectus filed with the Hong Kong Stock Exchange last month. Genrix (Shanghai) Biopharmaceutical Co. Ltd., meanwhile, has filed a patent application for a CD47 antibody.

Expanding pipeline

Beyond the CD47 front, I-Mab is working to expand its innovative drug pipeline. Last week, it in-licensed the greater China rights to an anti-B7-H3 monoclonal antibody known as enoblituzumab. B7-H3 is a target for which no agent is currently approved. (See *BioWorld*, July 12, 2019.)

The initial focus will be on squamous cell carcinoma of the head and neck, the most common type of head and neck cancer that is treated by cetuximab, the only approved drug in China.

"By acquiring the greater China rights of enoblituzumab, we hope to strengthen our clinical stage pipeline of innovative immune-oncology investigational drugs, including antibodies targeting CD47 and CD73," Jielun Zhu, chief financial officer at I-Mab, told *BioWorld*.

"As the only conventional B7-H3 antibody in clinical development worldwide, enoblituzumab has the potential to be a first-in-class anticancer immunotherapy for a variety of solid tumors that overexpress B7-H3," he added.

I-Mab will also see how it can combine enoblituzumab with other drug candidates in its pipeline to maximize its value, as so far enoblituzumab has already shown promising therapeutic potential in combination with PD-1 inhibitors. ♦

IPOs

Continued from page 1

helped bring the total of those offerings to 30 at the halfway point in the year. In terms of volume, the total was shy of the 35 U.S. biopharma IPOs completed in the same period last year, a number that was also bolstered by several new issues completed in June 2018.

Following the slow start, the second-quarter period proved to be quite hectic, with a total of 19 companies completing their IPOs, bringing the total raised year-to-date (YTD) to $3.3 billion, compared to the $3.5 billion raised in the first half of last year. (See *BioWorld Insight*, July 2, 2018.)

In a research note on biotech IPOs issued by Jefferies, analysts observed that "despite [a] volatile environment at start of the year . . . over 50% debuted within the past [two months] alone as appetite and performance has been good (and M&A in smid cap) – all fueling continued investor interest."

Early stage companies

Investors have even shown their willingness to get behind those companies that have yet to progress their products into clinical testing. At the end of June, Waltham, Mass.-based Morphic Holding Inc. raised a total of $103 million from its IPO, selling 6.9 million shares at $15 each, which included 900,000 shares sold upon full exercise of the underwriters' overallotment option. The company is focused on injectable drugs to treat autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. Its preclinical pipeline, including its lead program for alpha4beta7-specific integrin inhibitors affecting inflammation, is for treating inflammatory bowel disease. It is also developing MORF-720, a selective oral alphavbeta6-specific integrin inhibitor to treat idiopathic pulmonary fibrosis, in collaboration with Abbvie Inc.

The company's shares (NASDAQ:MORF) performed well on the first day of trading, closing at $18 per share, up 20%.

Bedford, Mass.-based Stoke Therapeutics Inc., which is developing RNA-targeted therapies for rare genetic diseases, is another preclinical company that closed its IPO, selling 9.07 million shares at $18 each for gross proceeds of approximately $163.3 million. Its lead product candidate, STK-001, is a potentially disease-modifying treatment for Dravet syndrome, a severe and progressive genetic epilepsy. It is currently in preclinical studies, with plans to initiate a phase I/II trial in the first half of next year. Its shares (NASDAQ:STOK) popped 42% on the first day of trading and they have since risen in value to almost 55% at the close of trading July 11. (See Biopharma IPOs in U.S. in 2019, page 10.)

A warm reception

The heightened enthusiasm for biopharma IPOs was clearly apparent at the end of the month from the warm welcome given to Adaptive Biotechnologies Corp. and Bridgebio Pharma Inc. (See *BioWorld*, June 28, 2019.)

Seattle-based Adaptive generated $345 million from its IPO, and its shares (NASDAQ:ADPT) ended their first day of trading at $40.30, up a whopping 102%, or $20.30.

Adaptive's clinical diagnostic product, Clonoseq, is the first test authorized by the FDA to detect and monitor minimal residual disease in patients with select blood cancers. With Microsoft, it is developing Immunoseq Dx, to enable early detection of many diseases from a single blood test. It has also entered a worldwide collaboration and license agreement with Genentech, a member of the Roche Group, to develop, manufacture and commercialize novel neoantigen directed T-cell therapies for the treatment of a broad range of cancers. Under the terms of the agreement, Adaptive will receive $300 million in an initial up-front payment and may be eligible to receive more than $2 billion over time, including payments upon achievement of specified development, regulatory and commercial milestones, and royalties on sales.

Bridgebio priced its IPO of 20.5 million shares of common stock at $17 each for gross proceeds of $348.5 million. Its shares (NASDAQ:BBIO) gained 62.1% on the first day of trading.

The Palo Alto, Calif.-based company said it will use funds to advance medicine to treat Mendelian diseases, which arise from defects in a single gene, and cancers with clear genetic drivers. It has four candidates in clinical trials. Two are in phase II, one is in phase II/III and one is in phase II.

Mixed performance

The strong performance of those companies has contributed to a collective 12% YTD increase in value of the new crop of biopharma public companies. Overall, the reception has been mixed, with only 14 trading in positive territory since their listings this year.

However, the return is certainly much better than those companies that went public in the first half of last year. That group of 34 companies (one company was acquired) are collectively trading down almost 30% since they listed.

Leading gainer in the 2019 IPO graduates is South San Francisco-based Cortexyme Inc., with a whopping 145.5% jump in its share value (NASDAQ:CRTX). It is focused on developing a disease-modifying therapeutic approach to treat a key underlying cause of Alzheimer's and other degenerative diseases.

Its lead drug candidate is COR-388, an orally administered brain-penetrating small-molecule gingipain inhibitor, which has completed phase Ia and phase Ib trials in patients with mild to moderate Alzheimer's disease (AD).

At this week's Alzheimer's Association International Conference (AAIC) in Los Angeles, the company said researchers will detail the rationale for and design of the GAIN trial, a phase II/III study of COR-388, in subjects with mild to moderate AD. The trial, the company said, is based on growing evidence that points to a key role for *Porphyromonas gingivalis*, the bacterium most commonly associated with chronic periodontal disease, in the development of AD, based on the identification of the bacteria in the brain of AD patients and its ability to cause neurodegeneration, inflammation, and other pathology associated with Alzheimer's in animal models.

Turning Point Therapeutics Inc., of San Diego, which closed its

See IPOs, page 11

Biopharma IPOs in U.S. in 2019

Company	Ticker	IPO price	Amount raised ($M)	Current price*	Market cap ($M)	% change
Adaptive Biotechnologies	ADPT	$20	$345	$37.64	4,638	88.2
Akero Therapeutics	AKRO	16	$105	$18.37	488	14.8
Alector	ALEC	$19	$175.75	$18.76	1,305	-1.3
Anchiano Therapeutics	ANCN	$11.50	$30.50	$4.55	32	-60.4
Applied Therapeutics	APLT	$10	$40	$8.10	138	-19.0
Atreca	BCEL	17	$124.95	$16.74	448	-1.5
Avedro	AVDR	$14	$70	$19.98	342	42.7
Axcella Health	AXLA	$20	$71.4	$8.21	193	-59.0
Bicycle Therapeutics	BCYC	$14	$60.70	$8.64	153	-38.3
Bridgebio Pharma	BBIO	$17	$348.50	$29.77	3,679	75.1
Cortexyme	CRTX	$17	$75	$41.74	1,120	145.5
Gossamer Bio	GOSS	$16	317.40	$21.05	1,387	31.6
Harpoon Therapeutics	HARP	$14	$75.60	$15.05	372	7.5%
Hookipa Pharma	HOOK	$14	$84	$8.84	191	-36.9
Hoth Therapeutics	HOTH	$5.60	$7	$5.52	53	-1.4
Ideaya Biosciences	IDYA	$10	$57.50	$8.04	163	-19.6
Inmune Bio	INMB	$8	$8.17	$9.80	101	22.5
Kaleido Biosciences	KLDO	$15	$75	$9.22	275	-38.5
Karuna Therapeutics	KRTX	$16	$102.60	$19.09	431	19.3
Milestone Pharmaceuticals	MIST	$15	$94.90	$21.46	468	43.1
Morphic Holding	MORF	$15	$103.50	$19.27	570	28.5
Nextcure	NXTC	$15	$86.25	$17.01	386	13.4
NGM Biopharmaceuticals	NGM	$16	$106.72	$13.95	937	-12.8
Precision Biosciences	DTIL	$16	$145	$14.30	715	-10.6
Prevail Therapeutics	PRVL	$17	$125	$12.13	412	-28.6
Stealth Biotherapeutics	MITO	$12	$85.10	$11.75	401	-2.1
Stoke Therapeutics	STOK	$18	$163	$27.85	878	54.7
TCR2 Therapeutics	TCRR	$15	$86.30	$13.19	316	-12.1
Trevi Therapeutics	TRVI	$10	$55	$7.21	129	-27.9
Turning Point Therapeutics	TPTX	$18	$191.5	$43.74	1,365	143.0

*July 11, 2019

Financings

Genmab A/S, of Copenhagen, Denmark, sold 28.5 million American depositary shares (ADSs), which represent 2.85 million ordinary shares of Genmab, in a U.S. IPO at $17.75 per ADS. The underwriters have a 30-day option to purchase up to 4.27 million additional ADSs. Gross proceeds from the sale are expected to be $505.9 million, or $581.8 million assuming full exercise of the option. BofA Merrill Lynch, Morgan Stanley and Jefferies are acting as joint book-running managers for the offering. Guggenheim Securities and RBC Capital Markets are acting as joint lead managers and Danske Markets, H.C. Wainwright & Co. and Kempen are acting as co-managers for the offering. ADSs of Genmab (NASDAQ:GMAB) closed up 43 cents, or 2.4%, to $18.18 after its first day of trading on Thursday.

Mirum Pharmaceuticals Inc., of Foster City, Calif., sold 5 million shares at $15 in an IPO, grossing the company $75 million that it plans to use for the development of maralixibat, an inhibitor of the apical sodium co-dependent bile acid transporter, for progressive familial intrahepatic cholestasis, Alagille syndrome and biliary atresia, and to advance development of volixibat, an ileal sodium bile acid co-transporter inhibitor, for intrahepatic cholestasis of pregnancy and primary sclerosing cholangitis. The underwriters have a 30-day option to purchase up to an additional 750,000 shares. Citigroup, Evercore ISI and Guggenheim Securities are acting as joint book-running managers for the offering. Raymond James is acting as lead manager, while Roth Capital Partners is acting as co-manager. Shares of Mirum (NASDAQ:MIRM) closed down $1.79, or 11.9%, to $13.21 after its first day of trading on Thursday.

Obseva SA, of Geneva, said its board approved an increase of its share capital from 45.5 million shares to 48.6 million. The shares will be listed on the SIX Swiss Exchange on or around July 23.

IPOs

Continued from page 9

$191.5 million IPO in April, has seen its shares (NASDAQ:TPTX) jump $143%. Its pipeline of tyrosine kinase inhibitors (TKI) targets numerous genetic drivers of cancer in both TKI-naïve and TKI-pretreated patients.

Last month, the company reported it has started the registrational phase II portion of its TRIDENT-1 study of patients with ROS1-positive advanced non-small-cell lung cancer and TRK-positive advanced solid tumors. Patients will be treated with Turning Point's lead kinase inhibitor, repotrectinib, which is being developed as a precision therapy targeting ROS1- and NTRK-driven cancers. Approximately 310 patients across five registrational cohorts will be enrolled in the study, with early interim results from initial patients being reported during the second half of 2020.

On the other side of the coin, Cambridge, Mass.-based Anchiano Therapeutics Ltd., formerly known as Biocancell Therapeutics Inc., which raised $30.5 million from its IPO of American depositary shares (ADSs) in February, has seen its shares (NASDAQ:ANCN) fall 60% in value.

Anchiano is working on a targeted gene therapy to improve the standard treatment for early stage bladder cancer. Proceeds from the offering, according to the company's first-quarter financial report, are expected to meet the company's capital needs until the second quarter of 2020. ♦

Clinical data for July 18, 2019

Company	Product	Description	Indication	Status
Phase I				
Macrogenics Inc., of Rockville, Md.	Flotetuzumab	Bispecific CD123 x CD3 DART molecule	Primary refractory acute myeloid leukemia	Completed enrollment of monotherapy expansion cohort; updated data expected in the second half of this year
Moleculin Biotech Inc., of Houston	Annamycin	Next-generation anthracycline	Acute myeloid leukemia	Interim data from phase I/II study showed 3 patients treated at dose level of 150 mg/m2 with no drug-related adverse events, including no signs of cardiotoxicity; drug safety review committee determined trial could progress to next higher dose level of 180 mg/m2
Phase II				
Anavex Life Sciences Corp., of New York	Anavex 2-73	Selective sigma-1 receptor agonist	Alzheimer's disease	Results from evaluation of gut microbiota of patients in ongoing phase IIa extension study showed those treated with Anavex 2-73 had high levels of 2 gut microbiota families, *Ruminococcaceae* and *Porphyromonadacea*e, which were associated with improved activities of daily living (ADCS-ADL) at week 148 ($p<0.01$ and $p<0.04$, respectively)
Bioarctic AB, of Stockholm, and Eisai Co. Ltd., of Tokyo	BAN-2401	Targets forms of amyloid beta	Alzheimer's disease	Subset analyses from a phase IIb study suggested treatment in patients with early disease was associated with reduced neurodegeneration at both 12 and 18 months; cerebrospinal fluid biomarker data showed impact downstream of the amyloid cascade, including reduction of tau pathology and synaptic function (neurogranin) and reduction in increase of axonal degeneration (neurofilament light chain)
Phase III				
Orphazyme A/S, of Copenhagen, Denmark	Arimoclomol	Amplifies production of heat-shock proteins	Amyotrophic lateral sclerosis	Completed enrollment ahead of schedule; headline results from full analysis remain on track for first half of 2021

Notes
For more information about individual companies and/or products, see Cortellis.

Regulatory actions for July 18, 2019

Company	Product	Description	Indication	Status
CTI Biopharma Corp., of Seattle	Pacritinib	JAK2 inhibitor	Myelofibrosis	Following type B, end-of-phase IIa meeting with FDA, CTI plans phase III study to test 200 mg administered twice daily in 180 patients with myelofibrosis and severe thrombocytopenia; Pacifica study set to start in third quarter of 2019
Horizon Therapeutics plc, of Dublin	Procysbi (cysteamine bitartrate) delayed-release oral granules in packets	Cystine-depleting agent	Nephropathic cystinosis	FDA accepted NDA for new dosage form; decision expected in 2020
Lifemax Laboratories Inc., of Palo Alto, Calif.	LM-030	Kallikrein-related peptidase inhibitor	Netherton syndrome	FDA granted rare pediatric disease designation
Sosei Group Corp., of Tokyo, and Formosa Pharmaceuticals Inc., of Taipei, Taiwan	APP-13007	Nanoparticle formulation of corticosteroid clobetasol	Postoperative inflammation of the eye	FDA cleared the IND for first-in-human trial
Transgene SA, of Strasbourg, France	TG-6002	Next-generation oncolytic virus	Colorectal cancer	U.K.'s MHRA cleared firm to proceed with phase I/IIa trial testing TG-6002 administered by intrahepatic artery infusion in patients with unresectable liver metastases

Notes
For more information about individual companies and/or products, see Cortellis.