


**Scrip Awards**   
Informa Pharma Intelligence

# The 15th Annual Scrip Awards 2019

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It was a real pleasure to host the 15th Annual Scrip Awards and honor the many achievements of the pharmaceutical, biotechnology, clinical research and allied sectors.

The 21st century is truly shaping up to be biopharma's golden age. With innovation in so many fields, from scientific progress in academia through the discovery of novel therapies to the use of big data, real-world evidence, artificial intelligence and other evolving tools to refine the drug development process, R&D has never been so diverse nor so exciting.

The pace of progress is such that regulatory and reimbursement systems must evolve rapidly to keep up. The development of new and better treatments is only meaningful if patients can access those treatments. Here again, the biopharma industry is applying its knack for innovation and collaboration to work with payers and health services to adapt existing market access frameworks and accommodate the new wave of advanced medicines.

At a time of such change, it is important to step back and acknowledge the tremendous achievements of the people who work every day to grapple with the formidable challenge of improving people's lives. The dedication of people in our industries has yielded breakthroughs that were once deemed impossible. The Scrip Awards celebrate your extraordinary accomplishments.

Thanks to all of you who entered – being on the shortlist is a real achievement and our judges had a difficult task in deciding the winners from a highly competitive line-up of entrants. The awards cover a broad spectrum of business activities, from clinical trials to new product launches, from financing to partnership and from drug development to drug launch. We also honor the teamwork and leadership that ensure the success of these activities.

Many of the celebrated R&D advances, deals and fundraising have been covered by Scrip over the past 12 months or so. Please enjoy this selection of recent articles that reflect the wide array of industry activities and the breadth of our coverage.

Eleanor Malone  
Editor in Chief, *Scrip*

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## ROLL OF HONOR 2019



The winners of the 15th Annual Scrip Awards  
were announced 4 December  
at The London Hilton on Park Lane.

We'd like to take this opportunity to thank everyone  
who entered and congratulations to the winners.

# THE 2019 SCRIP AWARDS WINNERS

## MSD'S INNOVATION AWARD

**Mogrify's Direct Cellular Conversion Technology**

## BEST TECHNOLOGICAL DEVELOPMENT IN CLINICAL TRIALS

**CluePoints' Risk-Based Study Execution and Data Quality Oversight Software for Clinical Trials**

## FINANCING DEAL OF THE YEAR

**Galapagos's \$345m secondary follow-on financing**

## BEST PARTNERSHIP ALLIANCE

**Cancer Research UK, LifeArc and Ono Cancer Immunotherapy Alliance**

## BEST CONTRACT RESEARCH ORGANIZATION – SPECIALIST PROVIDERS

**Quanticate**

## BEST CONTRACT RESEARCH ORGANIZATION – FULL-SERVICE PROVIDERS

**ICON**

## BUSINESS DEVELOPMENT TEAM OF THE YEAR

**Procter & Gamble's Business Development Team**

## WORLDWIDE CLINICAL TRIALS' LICENSING DEAL OF THE YEAR AWARD

**Innate Pharma and AstraZeneca's five-part deal including monalizumab in immuno-oncology**

## MASTERS SPECIALITY PHARMA'S BEST COMPANY IN AN EMERGING MARKET AWARD

**BeiGene**

## EXECUTIVE OF THE YEAR – FOR SMALL CAP & PRIVATE COMPANIES

**Ryan Cawood, founder and CEO of Oxford Genetics**

## EXECUTIVE OF THE YEAR – FOR LARGE & MEDIUM CAP COMPANIES

**Menelas Pangalos, EVP and president, R&D BioPharmaceuticals, AstraZeneca**

## IQVIA'S CLINICAL ADVANCE OF THE YEAR AWARD

**Novartis/AveXis' Phase III STR1VE study of Zolgensma in spinal muscular atrophy**

## MEDIDATA'S COMMUNITY PARTNERSHIP OF THE YEAR AWARD

**AstraZeneca's Energy Challenge**

## WUXI APP TEC'S BIOTECH COMPANY OF THE YEAR AWARD

**Galapagos**

## SYNEOS HEALTH'S BEST NEW DRUG AWARD

**Alnylam Pharmaceuticals' Onpattro (patisiran) for polyneuropathy of hereditary transthyretin-mediated amyloidosis**

## PHARMA COMPANY OF THE YEAR

**Takeda Pharmaceutical Co Ltd**

## SCRIP'S LIFETIME ACHIEVEMENT AWARD

**Jane K Osbourn OBE**



**Thank you to everyone who voted for us and for recognizing our innovation in the field of cardiovascular disease and elevated lipoprotein(a), or Lp(a)**

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Photo: The Lipoprotein(a) Foundation



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# IQVIA'S CLINICAL ADVANCE OF THE YEAR

## AKCEA



We are honored to be a finalist for IQVIA's Clinical Advance of the Year Award for our Phase 2 study of AKCEA-APO(a)-LRx in patients with cardiovascular disease (CVD) and elevated levels of lipoprotein(a), or Lp(a)

AKCEA-APO(a)-LRx is the first and only drug that has demonstrated in clinical studies a significant reduction in Lp(a) levels in patients living with CVD and elevated Lp(a) that cannot be well controlled with lifestyle modifications or existing cholesterol-lowering medications. This disease often impacts people in their 30's and 40's.

The Phase 2 study data represent an important advancement for patients as they demonstrated that treatment with AKCEA-APO(a)-LRx resulted in statistically significant and dose dependent reductions from baseline in Lp(a) levels. The data demonstrated proof of concept of AKCEA-APO(a)-LRx and show how Ionis' advanced antisense technology can have an impact in a disease with no approved therapies.

Thank you to Scrip for this important recognition.

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THERAPEUTICS

# Takeda: 12 NMEs Poised To Launch In Five Years And Deliver \$10 Bn In Peak Sales

JESSICA MERRILL



**T**akeda Pharmaceutical Co. Ltd.' efforts over the last five years to reshape its pipeline – including the merger with Shire PLC – are now poised to deliver. The Japanese pharma held its first ever investor day in New York on 14 November, coming after the company's stock was listed on the New York Stock Exchange in 2018 and the merger with Shire was completed in January.

With the integration of Shire largely completed, Takeda CEO Cristophe Weber, R&D president Andy Plump and other R&D leaders set out to showcase the Takeda's progress in reenergizing the pipeline with a focus in four core areas: oncology, rare diseases, gastroenterology and neuroscience.

"It's a very special moment because it's not just a pipeline update," Weber told investors. "It's how the R&D strategy that we developed five years ago is coming together."

Weber took over as CEO of Takeda in 2014 as the first non-Japanese executive to hold the top leadership spot at the company, and with big ambitions to globalize the company. He brought in new leaders like Plump, who previously worked at Sanofi, to streamline and revitalize R&D. With the \$61bn acquisition of Shire, Takeda built out the commercial portfolio and R&D pipeline in rare diseases and established itself as a top 10 pharmaceutical player, based on pharmaceutical revenues, with revenues of more than \$31bn.

Takeda revealed 12 potential new molecular entities that could launch in the next five years, through its fiscal year 2024, which could together deliver \$10bn in peak sales. Takeda is calling these 12 NMEs "Wave 1," which will be followed by "Wave 2," made up of 26 earlier-stage NMEs that could launch in fiscal year 2025 and beyond.

"Reflecting back on five years from when I came, if I were to look at Takeda then and Takeda now, with the exception of the values and this iconic, rich history that lives with us every day, it's an unrecognizable company," Plump said.

For one thing, Takeda has greatly diversified the types of drug modalities in its R&D engine, from what was largely all small molecules to what is now 70% diversified modalities, including biologics, cell therapy, gene therapy, peptides and microbiome-targeted therapies.

Of the 12 NMEs included in Wave 1, half are expected to launch further out in the cycle, in 2023 or 2024, however.

Among the nearer-term pipeline candidates that could launch in fiscal 2020 or 2021 are two

that came via Shire: TAK-721 (budesonide oral suspension) for eosinophilic esophagitis (EOE), an immune-mediated rare disease effecting the esophagus for which there are no treatments, and TAK-620 (maribavir) for cytomegalovirus infection following a transplant. The acquisition of Shire added 18 new NMEs to the pipeline.

The first of two Phase III studies studying TAK-721 read out positively in October. Two pivotal studies testing TAK-620 are ongoing, with Phase III data in patients receiving a solid organ transplant or hemopoietic stem cell transplant expected to read out in the second half of 2020.

### Progress In Oncology

In oncology, Takeda has made notable strides. The company has a strong foundation in cancer, stemming from the acquisition of Millennium BioTherapeutics Inc. in 2008, which gave the company the backbone multiple myeloma therapy Velcade (bortezomib), now available generically. Takeda currently markets the follow-

on proteasome inhibitor Ninlaro (ixaxomib) for multiple myeloma, and it further expanded the commercial portfolio with the 2017 acquisition of Ariad Pharmaceuticals Inc. for \$5.2bn, which added Iclusig (ponatinib) and Alunbrig (brigatinib). (Also see "Takeda Acquires Ariad In \$5.2bn Deal – US Infrastructure A Key Component?" – Scrip, 9 Jan, 2017.)

Nonetheless, Takeda missed out on the first wave of immuno-oncology drugs – the checkpoint inhibitors and cell therapies.

The head of Takeda's oncology drug discovery unit Chris Arendt outlined how the company has pivoted to assemble a pipeline with a core focus on immuno-oncology with curative intent, and has particularly built a novel cell therapy platform. A big component of the strategy has been partnering externally.

"We've been able to leapfrog into new modalities and leapfrog into exciting new mechanisms," Arendt said. "We are working on differentiated oncology concepts and a big theme across our portfolio



1. Projected timing of approvals depending on data read-outs; some of these Wave 1 target approval dates assume accelerated approval  
2. Some Wave 2 assets could be accelerated into Wave 1 if they have breakthrough data  
3. Projected approval date assumes filing on Phase 2 data  
4. TAK-079 to be developed in Rare Diseases indications myasthenia gravis (MG) and immune thrombocytopenic purpura (ITP) (ITP) projected in each indication in 2H FY19)

Orphan potential in at least one indication  
Estimated dates as of November 14, 2019

is leveraging very powerful cells of the immune system, which are the innate immune cells that really orchestrate everything that happens in an immune response.”

Some of the results of that work, however, are part of Wave 2, which is expected to reach the market after fiscal 2024, including the first-in-class SUMO inhibitor TAK-981, based on an internal SUMOylation platform, and TAK-573, based on the Attenukine platform that elicits both direct tumor kill and immune activation, using a engineered version of type 1 interferon targeted to tumor cells via a CD38 antibody.

Jefferies analyst Stephen Barker applauded the company's efforts in oncology. “Takeda's adoption of an outward-facing innovation model has enabled Takeda to make a great leap forward to the forefront of cell-based immuno-oncology,” he said in a 15 November research note. “Rather than follow the crowd into checkpoint inhibitors and CAR-T cell therapies, Takeda has blazed a new path.”

### **Commitment To Cell Therapy**

The company's emerging cell therapy pipeline got a lot of attention during the overview, with Arendt highlighting Takeda's focus on gamma delta T-cells and natural killer (NK) cells. The company expects to have five cell therapy programs in clinical testing by the end of fiscal 2020.

### **The company expects to have five cell therapy programs in clinical testing by the end of fiscal 2020.**

The company formed a cell therapy translational team in July 2018 under the leadership of Stefan Wildt, who helped deliver Novartis AG's CAR-T therapy Kymriah to market. (*Also see “New Takeda R&D Collabs Aim To Boost IO Pipeline” - Scrip, 4 Jan, 2019.*)

“He's put together a best-in-industry team and opened a GMP manufacturing suite now in our Cambridge campus and will be helping us not only accelerate these cell therapies to that early clinical setting, but to make sure that we capture and leverage those incredible translational learnings that will inform the many iterations that are possible in this space,” Arendt said.

Takeda announced earlier in November an exclusive licensing agreement with MD Anderson Cancer Center to develop cord blood-derived CAR-directed NK cell therapies, engineered with IL-15, for the treatment of B-cell malignancies and other cancers. (*Also see “Asia Deal Watch: Ambrx, NovoCodex Partner On Second ADC Candidate, For CD70-Positive Cancers” - Scrip, 6 Nov, 2019.*) The first of the programs, TAK-007, is already in the clinic and will be going forward in CD19-positive malignancies, with an eye toward entering pivotal studies in 2021. In a patient with diffuse large B-cell lymphoma (DLBCL) who had failed three lines of prior therapy, after being treated with TAK-007 he achieved a complete response after just one dose.

“Our vision for this product is to be able to provide patients with a highly efficacious CAR NK immunotherapy that has a safety profile allowing it to be administered in an outpatient and community setting,” Arendt said. The first CAR-T cell therapies are associated with serious adverse events, including cytokine release syndrome, and require administration in a hospital setting.

Despite the excitement over cell therapy, Takeda has two assets that are significantly closer to commercialization: TAK-788 for patients with EGFR non-small cell lung cancer with exon 20 insertion mutations and the NEDD8 inhibitor TAK-924 (pevonedistat) for myelodysplastic syndrome. Both are anticipated to reach the market in the 2021 timeframe.



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# Citeline Awards 2020

Thursday, April 30, 2020

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# For An Ultra-High-Priced Drug, Alnylam Brings A New Idea

JESSICA MERRILL

**A**lnylam Pharmaceuticals Inc. is introducing a novel prevalence-based pricing adjustment for payers to support the launch of its newly approved Givlaari (givosiran), which will come with a high price tag. Givlaari was approved by the US Food and Drug Administration on 20 November for the rare genetic disorder acute hepatic porphyria (AHP), which affects just a few thousand patients in the US and Europe.

The drug will launch with an ultra-high price tag as well: \$575,000-per-patient-per-year before discounts. The company told investors to expect a net price more in the range of \$425,000 after discounts and rebates.

In a proactive move to counter potential pushback from payers, Alnylam said it will offer a prevalence-based adjustment feature that will trigger rebates to participating payers if the number of diagnosed patients they cover exceeds current epidemiologic estimates for AHP.

There are only about 1,000 patients in the US and EU who have recurrent attacks, which can result in severe pain, neurological damage and death. The company believes it could target another 5,000 patients in the two regions who experience sporadic attacks and chronic manifestations. (*Also see "Alnylam Ramps Up Commercial Planning For Givosiran Based On Phase III Data" - Scrip, 6 Mar, 2019.*) The company guided analysts to forecast about 3,000 patients in both regions initially.

As is frequently the case with drugs for rare diseases, the prevalence rates aren't always fully understood, and diagnosis rates are low until there is a new treatment to spur diagnosis. Often, in such cases, drug makers base their pricing on the initially low prevalence figures only

to find the number of patients is higher than expected, which then becomes an issue for payers.

During a same-day conference call, Alnylam president Barry Greene said it is the first drug company to introduce a prevalence-based adjustment feature to payers, as far as it is aware. The company said the decision was driven by a desire to be "proactive" and bring a new idea to the negotiating table.

"This innovative approach offers greater certainty to payers that their overall financial risk will be adjusted if a substantially larger number of patients than currently estimated are identified," Alnylam said.

In addition, CEO John Maraganore said the new feature is part of a risk-sharing arrangement with payers. "We do require the payer to also reimburse the product for the label, not to restrict reimbursement to some clinical trial components," he pointed out.

The launch will also be supported by a more traditional value-based reimbursement agreement for both government and commercial payers in which they will pay the full value for Givlaari only when it delivers patient outcomes similar to what was demonstrated in the ENVISION clinical trial supporting FDA approval. In the 94-patient ENVISION trial, patients who received Givlaari experienced 70% fewer porphyria attacks compared to patients taking placebo.

Greene said the company's pricing decision was driven by the ultra-orphan nature of the disease and the high cost of helping patients currently, which can reach \$400,000 to \$650,000 annually, including hospitalization and hemin administration.

Alnylam said it has already reached one coverage agreement with Harvard Pilgrim covering Givlaari and is working with others.

# Early Assets Excite At Novartis R&D Day

KEVIN GROGAN



Novartis AG has presented a detailed look into both early and late-stage assets which it believes could produce 25 potential blockbusters. At an investor R&D event in London on 5 December, the Swiss major highlighted 60 projects in Phase II, of which at least ten are expected to advance into Phase III each year in 2020 and 2021. Over 90% are projected to be first-in-class or first-in-indication.

Speaking to a small group of journalists hours before the investor event, Jay Bradner, president of the Novartis Institutes for BioMedical Research (NIBR), said "the stars are aligned...because our ability to invest in R&D is directly correlated to the financial performance of the company. These have really been the salad days so in the labs right now, there's quite a lot of optimism and enthusiasm and the productivity is really remarkable."

Head of the part of Novartis that discovers drugs and typically takes them up to Phase IIa, Bradner highlighted the firm's portfolio of early-stage molecular glues led by TNO155, a first-in-class SHP2 inhibitor. He said this "could be a really big deal" to treat solid tumors and based on preclinical data, has proved to be "powerfully synergistic" with KRAS inhibitors that are being developed for G12C-mutated, non-small cell lung carcinoma.

Novartis announced an agreement in July with Mirati its KRAS G12C inhibitor to test MRTX849 in combination with TNO155. It also made a recent investment in KRAS inhibition for its own portfolio, partnering with Cancer Research UK. (Also see "Mirati's First KRAS Data Look At Least As Good As Amgen's" - *Scrip*, 29 Oct, 2019.) (Also see "Novartis Snaps Up KRAS Inhibitor R&D" - *Scrip*, 24 Oct, 2019.)

Bradner also spoke about intermolecular glues,

which stick two proteins together. A good example of those are protein degraders, molecules “that take a target protein that’s maybe even undruggable and they glue it to the disposal system of the cell to take out the trash and destroy that protein.” This is the scientific program he runs when not on NIBR leadership duty, and one protein degrader has just entered the clinic, “with a very strong pipeline behind it.”

He said, “We’ve put a huge emphasis on first in class. It may seem obvious but most of biopharmaceutical research is fast-follower research. This illusion of best in class, which I regard as a surrogate for not first in class, is pervasive in our ecosystem and you may know the term ‘the best source of new drugs is old drugs.’ We reject that hypothesis.”

### Highest Hanging Fruit

Saying that Novartis’s strategy is “to reach for the highest hanging fruit,” Bradner said that “the core of our research engine is now fully rebuilt.” This required a change on cultural expectations and management teams “and most importantly, prioritization of our portfolio - research and development were regrettably at quite a distance before.”

The portfolio has been overhauled “to engender rapid transit from the labs into the clinics and into the marketplace, through clarified and uniform strategies like you would expect from a vertically-integrated organization,” he said. “We’ve also markedly reduced the scope in order to increase resourcing,” with 430 drug discovery projects being trimmed to about 325.

The R&D day also saw Novartis highlight projects that should be advancing into pivotal trials in the coming years. First up was iscalimab, a monoclonal antibody (mAb) against the CD40 receptor which the firm believes has the potential to become the standard of care in transplant. It has also demonstrated positive proof-of-concept in Sjögren’s syndrome, and trials are being initiated in six separate indications. (Also see “Can Novartis Reclaim Pioneering Role In Transplantation?” - *In Vivo*, 2 Oct, 2019.)

Also causing excitement was LNP023, an oral factor B inhibitor which targets the alternative complement pathway. Novartis claimed that early Phase II data support advancing the drug as a first-line treatment for the rare blood disorder paroxysmal nocturnal hemoglobinuria (PNH).

**Saying that Novartis’s strategy is “to reach for the highest hanging fruit,” Bradner said that “the core of our research engine is now fully rebuilt.”**

Full Phase IIa/IIb readouts are expected next year and 2021 for LNP023. It is in development for three rare renal diseases - IgA nephropathy, membranous nephropathy and C3 glomerulopathy.

In immuno-oncology, the Basel-based group touted MBG453 as a first-in-class anti-TIM-3 mAb which it thinks has the potential to become a foundational therapy across myeloid diseases. It is currently in a pivotal Phase II program in myelodysplastic syndrome, with Phase I data to be presented at the imminent American Society of Hematology (ASH) meeting in Orlando.

Another asset that will be moving into Phase III into late-stage trials next year is TQJ230, an antisense oligonucleotide to reduce lipoprotein(a) a currently untreatable risk factor for cardiovascular disease. A CV outcomes trial of over 7,500 patients evaluating the RNA-targeting lipid-lowering candidates recently licensed from Ionis Pharmaceuticals Inc. affiliate Akcea Therapeutics Inc. is planned to start in 2020.

The drug is key to Novartis’s CV efforts which have just received a boost with its proposed \$9.7bn acquisition of The Medicines Company and the latter’s closely-watched siRNA drug inclisiran. (Also see “It Has Been A Long Farewell To The Medicines Company” - *Scrip*, 26 Nov, 2019.)

# It Has Been A Long Farewell To The Medicines Company

JESSICA MERRILL

**N**ovartis AG's acquisition of The Medicines Co. for \$9.7bn is a healthy exit for the company's investors, but the company Novartis is buying is a streamlined, unrecognizable version of the hospital specialist The Medicines Company once was.

In less than five years, The Medicines Company went through a dramatic makeover, transitioning from a multi-product, revenue-generating drug company to a single asset drug developer on the quest for a buyer.

Now the company's product is poised to be integrated into Novartis, and The Medicines Company will wind down after 23 years of business. The Swiss pharma announced it had struck a deal to acquire the company on 24 November. (*Also see "Novartis To Pay \$9.7bn For The Medicines Company" - Scrip, 24 Nov, 2019.*)

Clive Meanwell, The Medicines Company's founder and longtime CEO, was the architect behind the company. He founded The Medicines Company in 1996, with the financial backing of investment firms MPM Capital and Warburg Pincus, to develop late-stage drug candidates shelved by bigger biopharmas. Over the next 20 years, he built the company into a multi-product hospital specialist, generating hundreds of millions in sales, largely through acquisition.

One of the first candidates Meanwell brought in was the company's eventual best seller, bivalirudin, the drug that became Angiomax, which it gained through a licensing deal with Biogen Inc. in 1997 for \$30m up front. The company had eight employees at the time. It went public in August 2000, and Angiomax was approved by the US Food and Drug Administration months later.

Meanwell stepped aside late last year, however, to



make way for a new CEO, Mark Timney, to be the architect of a different strategy: to broker a sale. (*Also see "The Medicines Co. Names Mark Timney As CEO In A Shakeup" - Scrip, 11 Dec, 2018.*) By then, the company had an activist investor, Alex Denner, chairing its board and had sold off all of its commercial-stage drugs to focus investment on the development of its sole clinical candidate, the Phase III RNA-interference drug inclisiran for high cholesterol. That's the drug Novartis believes it can commercialize into a mega blockbuster. (*Also see "Novartis Sees Reimbursement Advantage For PCSK9 Launch" - Scrip, 25 Nov, 2019.*)

Inclisiran came into the company's portfolio in February 2013 through a development and commercialization alliance with Alnylam Pharmaceuticals Inc.. Under the agreement, The Medicines Company paid just \$25m up front in cash and agreed to pay \$180m in development and commercial milestone fees, and royalties on sales. The Medicines Company was responsible for leading and funding development from Phase II.

That deal turned out to be a pivotal turning point for the company. As commercial prospects for some of the company's other big sellers dried up and

development assets fizzled, investors focused the lens increasingly on inclisiran.

### **A Hospital Business Strategy Stumbles**

The Medicines Company's revenues peaked in 2014, when the company generated \$724.4m in revenues, driven largely by the blood thinner Angiomax (bivalirudin) and other products like the surgical clot promoter Recothrom (thrombin) and new antibiotic launches Orbactiv and Minocin (minocycline).

Angiomax, a blood thinner used during percutaneous coronary intervention (PCI) procedures, was the company's crown jewel. It generated the vast majority of sales, \$635.7m in 2014, and The Medicines Company's growth strategy hinged on its continued success.

Patent challenges from generic drug makers cast a long shadow over that strategy, however, and in 2015 it crumbled altogether when an appeals court ruled rival Hospira Inc.'s generic drugs did not infringe The Medicine Company's patents. In an enormous blow to the company, generic versions of Angiomax launched four years earlier than expected.

Meanwhile, another drug the company was developing faced a setback around the same time – Kengreal (cangrelor). The drug was approved by FDA in June 2015 as an adjunct to PCI to reduce the risk of myocardial infarction, repeat coronary revascularization and stent thrombosis, but only in a narrow patient population, a disappointment for its commercial prospects.

The company also had invested substantially in the development of novel antibiotics, including with the 2013 acquisition of Rempex Pharmaceuticals Inc. for \$140m up front plus earn-outs. That deal eventually led to the FDA approval and launch of Vabomere (meropenem/vaborbactam) for complicated urinary tract infections, but the commercial dynamics for novel antibiotics are challenging.

### **Pivoting To A New Strategy**

After the Angiomax patent ruling, the company immediately halted promotional activities, redeployed some sales reps and cut 100 employees

to reduce costs. Its revenues in 2015 declined by more than half, to \$309m. By 2017, the company's revenues were only \$44.8m as the company had by then pivoted to a new strategy that really began with that court decision.

"It's time for us to move on, and we have," Meanwell said during the company's second quarter earnings call in 2015, weeks after the court ruling. He then mentioned an idea that would solidify into a core part of the company's strategy for the next three years – partnering and divesting assets.

"We're seeking partners for global and/or ex-US investment in our new products and R&D programs," he said. "With Angiomax uncertainty now resolved, we believe we can secure deals that advance our pipeline, defray development expenses, expand the clinical and commercial potential of our products and create value for our shareholders."

In 2016, the company sold much of its cardiovascular portfolio to Chiesi Farmaceutici SPA, including Kengreal, Cleviprex (clevidipine) and argatroban, in exchange for \$264m in cash and \$480m in sales-based milestone payments.

In November 2017, after The Medicines Company moved inclisiran into Phase III clinical development, the company reached a deal to sell its infectious disease business to

Melinta Therapeutics Inc. for \$270m in cash and stock. (*Also see "Melinta Expands Portfolio, TMC Narrows Focus To LDL Reduction With Anti-Infective Deal" - Scrip, 29 Nov, 2017.*) The antibiotics specialist is now facing financial uncertainty, suggesting that The Medicines Company made a savvy decision exiting the space.

Now what's left of the company is poised to be sold to Novartis, and for a lot of money. Novartis believes inclisiran, as a more convenient, more affordable PCSK9 option, will become one of its best sellers. The Medicines Company's management has indeed executed on that plan to create value for shareholders, though not the way it had initially intended.

# Interview: AstraZeneca 'Is More Than Oncology'

STEN STOVALL

While clearly enjoying the rewards of its strengthening oncology portfolio, AstraZeneca PLC also used its third-quarter results update 24 October to stress that its two other therapeutic pillars - respiratory and CVRM - are performing well and hold great promise.

"Yes, we are very proud of our oncology performance at AstraZeneca, but equally we're trying to signal that AstraZeneca is much more than oncology and that we have an incredible pipeline, both in respiratory and CVRM (cardiovascular, renal and metabolism)," said Ruud Dobber, who heads the UK group's biopharmaceuticals operations. "And that's by purpose, because we don't want to be too dependent on one therapeutic area. That strategy is working out nicely," he said in an interview.

This year's third quarter "was one of the busiest periods in our pipeline, with four regulatory approvals in biopharmaceuticals, and the release of eight major Phase III studies," Dobber noted.

The double-barreled biopharmaceuticals business now generates 41% of AstraZeneca's total revenues. In the year's first nine months, CVRM sales grew 14% year-on-year while respiratory sales advanced 13%.

"This business is growing at double digits, which is not always a given for products like these," he said.

"Moving forward, our pipeline is very strong in both therapeutic areas ... I cannot overemphasize the importance of these two therapeutic areas for this company," Dobber said.

## Respiratory Trio Highlighted

He highlighted to *Scrip* prospects for the biologic tezepelumab, which AstraZeneca is developing in partnership with Amgen Inc., and two other respiratory pipeline assets which he believes have huge potential.



**"Yes, we are very proud of our oncology performance at AstraZeneca, but equally we're trying to signal that AstraZeneca is much more than oncology and that we have an incredible pipeline" – Ruud Dobber**

*(Also see "Tezepelumab Deemed Breakthrough But Can Phase III Reproduce Data?" - Scrip, 7 Sep, 2018.)*

"Next year we expect the Phase III outcome of tezepelumab which is potentially a best-in class biologic for severe, uncontrolled asthma. And we are in the process hopefully next year of getting PT010, which is called Breztri Aerosphere in Japan, registered

in both Europe and the US next year, and we are also developing a very unique product for the United States called PT027 as a treatment for early-stage asthma," he said. PT027 is investigational fixed-dose combination of budesonide, which is an inhaled corticosteroid, and albuterol, a short-acting beta-2 agonist.

### Therapeutic Synergies

Dobber said the company's drug development efforts were revealing synergies between cardiovascular, renal and metabolism as a co-related therapeutic focus for organ protection.

"What we have learned is that, if you take the heart, if you take the pancreas, and you take the kidney, there is more and more scientific evidence that those three organs are working almost in concert with each other and if you intervene at the level of the kidney, that gives a positive effect on the heart. We call it 'Cardiovascular, Renal and Metabolism' for that reason, in that there's an interlink between the three organs."

He noted that AstraZeneca's Farxiga, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, is now being marketed in the US to reduce the risk of hospitalization for heart failure (hHF) in patients with type 2 diabetes, making it the first drug in its class to win a heart failure indication outside of diabetics with renal co-morbidities. *(Also see "AstraZeneca's Farxiga Approval In Heart Failure A First For SGLT2 Inhibitors" - Scrip, 22 Oct, 2019.)*

While the Johnson & Johnson and Eli Lilly & Co./Boehringer Ingelheim International GmbH drugs have a lead over Farxiga with their CV risk reduction indications, Farxiga may be the first SGLT2 inhibitor to market as a heart failure treatment for patients regardless of whether they have diabetes. AstraZeneca has said it will seek a broad heart failure indication in the first half of 2020 based on the DECLARE-TIMI 58 and DAPA-HF studies.

Janssen Pharmaceutical Cos.'s sodium-glucose co-transporter 2 (SGLT2) inhibitor Invokana (canagliflozin) specifically carries an indication to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death and hospitalization for heart failure

in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria. *(Also see "Keeping Track: US FDA, Industry Roar Into Fourth Quarter With Bevy Of Regulatory Announcements" - Pink Sheet, 5 Oct, 2019.)*

Jardiance (empagliflozin), the SGLT2 inhibitor from Eli Lilly/Boehringer Ingelheim, was the first drug in the class approved to reduce cardiovascular risk in type 2 diabetes based on the EMPA-REG outcomes trial in 2017.

Dobber said that studies conducted on the three SGLT2 inhibitors at the behest of regulators "show that Farxiga and its two other competitors in the class are not only safe, but that they also have a protective effect on the heart, leading to less death in patients with diabetes ... And we have also shown that Farxiga very substantially reduced hospitalization for heart failure, not only in type 2 diabetic patients but also in non-diabetic patients."

He said Farxiga had also shown itself to have a profound effect on the kidney, "by curbing the slowdown of kidney function."

"We are gradually moving to a space where SGLT2 inhibitors - and Farxiga in particular - are renal protective when compared with other products that are only focusing on lowering glucose in the body," Dobber said.

AstraZeneca still plans a US filing for its hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) roxadustat for the treatment of anemia in chronic kidney disease. Dobber declined to say whether AstraZeneca would use a priority review voucher which it acquired from Swedish Orphan Biovitrum AB for \$95m earlier this year for roxadustat's filing. *(Also see "AstraZeneca Buys Priority Review Voucher With Two Big Filings On The Horizon" - Scrip, 22 Aug, 2019.)*

"We have a priority review voucher, but so far we haven't decided yet which product we are going to use it for. We are now in a situation that the pipeline is now performing so extremely well that we have multiple choices where we could use the voucher," the executive said. He also declined to say what assets might be front runners in possibly using the priority review voucher.



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# PHARMA COMPANY OF THE YEAR

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*Pictured left to right: (1) Eleanor Malone, Editor in Chief, Scrip (2) Julie Kim, President, Plasma-Derived Therapies Business Unit; (3) Mwana Lugogo, Chief Ethics & Compliance Officer; (4) Andy Plump, President, Research & Development; (5) Fiona Bruce, broadcaster.*

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# Galapagos CEO Interview: Independence Allows Us To Keep Innovating

KEVIN GROGAN

**W**ith the ink barely dry on a \$5bn expansion of his company's pact with Gilead Sciences Inc., Galapagos NV CEO Onno van de Stolpe has told *Scrip* that the deal guarantees the closely watched Belgian biotech's independence for the long term.

Galapagos is banking an impressive \$3.95bn upfront and a \$1.1bn equity investment from Gilead, which has taken the alliance rather than acquisition route to bolster its pipeline. Indeed, if the US company had tried to buy Galapagos, it would have been shown the door pretty quickly.

Van de Stolpe said that it was to be expected that there would be M&A rumors swirling around but stressed that "over the years I have been very vocal, this is absolutely non-negotiable, an acquisition is unacceptable and unwanted and apparently that actually helps. In the whole 20-year history of Galapagos we have been approached about an acquisition only once, by a fellow biotech and that was years ago, and never by big pharma."

However, while management may say there is no chance of a sale, shareholders might view things differently, he acknowledged. "If a bid comes on the table, it becomes unstoppable and you lose the company," van de Stolpe said, citing the process that saw fellow Belgian biotech Ablynx NV get acquired by Sanofi last year.

Indeed it was the Ablynx sale that stirred the Galapagos CEO into thinking that "it's my responsibility to make sure that we secure our independence anchors," and the deal with Gilead serves that purpose. "The model is good for us, good for Gilead and good for the European biotech sector, this is how deals should be structured," he told *Scrip*. Gilead has upped its stake in Galapagos



**"Over the years I have been very vocal, this is absolutely non-negotiable, an acquisition is unacceptable and unwanted and apparently that actually helps. In the whole 20-year history of Galapagos we have been approached about an acquisition only once, by a fellow biotech and that was years ago, and never by big pharma" – Onno van de Stolpe**

to 12.3% to 22% and that can go as high as 29.9% but no more as the deal includes a 10-year standstill clause that prevents a buyout.

This enables Galapagos to build out its innovation over that period without any external restrictions, van de Stolpe said. "Gilead has no say in what disease areas we study, what targets we go after, the designs of our Phase II trials, we can go in any direction we want unhindered."

Gilead will have an opt-in for a host of Galapagos compounds to go into Phase III "and even if we disagree there, we have the final say," he added. Central to the pact "is the idea of independence and innovation. I think that's great."

One of Galapagos's goals will be to accelerate development of its Toledo program which went into the clinic at the beginning of 2019 and has shown "unprecedented activity in various inflammatory preclinical models with compounds targeting the class." Toledo is the code name for a novel class discovered by the firm which has a dual mode of action, stimulating anti-inflammatory cytokines and inhibiting pro-inflammatory cytokines. Van de Stolpe said the idea, if everything goes well in Phase I, is to initiate seven or eight parallel mid-stage trials next year and "this is the Galapagos way: if we think this is something that we should put our cards on, we do it big time."

As well as boosting Galapagos research war chest, and the company is expected to roughly double the size of its R&D team from 500 to 1,000 employees, the Gilead cash will accelerate the commercial build-up of the firm in Europe.

When reminded by *Scrip* about an interview in March this year where he said that "if you want to be seen as serious as a company you need to have a commercialization organization," van de Stolpe chuckled and stressed that "you've got to book sales. You can live from royalties but investors want to see a company that sells. We are giving up quite a bit in the US, but we'll get some very nice royalties and you have got to be realistic, you cannot build up a global infrastructure in two or three years so we'll focus on

making sure we get the infrastructure right in Europe."

The first task will be to prepare for Galapagos and Gilead's closely watched JAK inhibitor filgotinib for rheumatoid arthritis which should be filed in the US this year and Europe in 2020.

The two firms will co-commercialize in France, Italy, Spain, Germany and the UK, with Galapagos sharing global development costs 50/50 with Gilead, as against the prior 80/20 split. It is setting up a 40-person European commercial outfit and has exclusive rights in Belgium, the Netherlands and Luxembourg.

### Analysts Impressed

The response from analysts to the deal has been positive, although Hugo Solvet at Bryan Garnier argued in an investor note on 15 July that "the independence of Galapagos will have to be nuanced in our view as Daniel O'Day will join the board," along with another Gilead representative. Analysts at SVB Leerink issued a note saying that "everyone gets their cookies," with Gilead getting an immunology and inflammation pipeline and Galapagos being allowed "to remain independent as they focus added resources on expanding an already world-class discovery platform."

The broker went on to gush about Galapagos, saying that "our value thesis has always been a view of them as a technical powerhouse with heart, rather than on any one asset. Onno and team have carefully built Galapagos over two decades, focused intently on a 'science-first' mindset, and with a passion for standing up world class biotechnology in Europe."

Leerink added that "the pipeline is enthusiastically pursuing difficult targets in white spaces, building, morphing and leveraging their carefully built in-house discovery and chemistry." Gilead's 'option to buy' compounds "further validates this thesis," the analysts argued, as it shows a desire to "commit to pipeline and science, leave the people alone, support infrastructure build-up in Europe and elsewhere. Why? Because building an organization is exceptionally hard, destroying it disarmingly easy."

# How To Pay For The New Wave Of Gene Therapies

FRANCESCA BRUCE



**A**s more gene therapies outside the oncology and rare disease space come to the market, strategies for paying for these expensive treatments are set to evolve. “An ongoing and wide-ranging discussion is needed about the assessment, payment and reimbursement of innovative products, as well as the evidence that supports them,” said Paul Goudreau, executive director & head of Phase IV Solutions at the CRO Covance.

Several expensive gene therapies, for example Novartis’s Kymriah and Gilead’s Yescarta, have already come to market. So far they are largely indicated for treating rare diseases and different types of cancer.

However, the gene therapy space is opening up to indications outside these disease areas, according to

Goudreau. A search of [clinicaltrials.gov](https://clinicaltrials.gov) in February showed that there were 140 industry sponsored trials that were either active or recruiting, he said. 34 of those studies were in non-rare disease/non-oncology indications, including diabetic neuropathy, hemophilia A, hemophilia B, Parkinson’s disease and HIV.

These treatments are likely to come with lower prices than rare disease or oncology gene therapies because of the larger patient populations and wider usage, Goudreau said in an interview. However, he added that prices are still likely to be relatively high compared with other new medicines because of the greater development costs associated with gene therapies.

“We do, however, expect the emergence of new models of payment and assessment to deal with these types of treatments, particularly as their numbers increase and the potential for use becomes more widespread,” said Goudreau.

## Problems With Current Mechanisms

A survey by Covance shows that existing pricing and reimbursement mechanisms are lacking when it comes to evaluating gene therapies.

That survey gathered the views of stakeholders in Germany, Sweden and the UK who are or who have been responsible for making pricing decisions on a national, regional and local level. The countries were selected to represent a variety of perspectives on reimbursement. For example, in Germany, assessments focus on clinical benefit, not cost-effectiveness, while in the UK, cost-effectiveness is the main focus. In Sweden assessments focus on cost-effectiveness from a societal perspective.

Some 68% of respondents said that existing national pricing and reimbursement mechanisms

were inadequate for evaluating potentially curative gene therapies. 32% believed current systems were adequate, and the rest were undecided.

They cited limitations with their systems, including time consuming processes and the challenges of managing uncertainty around the long-term effects of therapies. Respondents also reported concern that decisions taken at a national level could be hard to implement on a local level, for example because of local budget constraints.

The biggest obstacle to health systems purchasing gene therapies was reported to be the actual budget impact. "From a health economics point of view, we are likely to see treatments that are considered to be cost-effective, ie, offer value for money, but cannot be covered under current budgets, ie, are not affordable," Goudreau said.

### Possible New Models

Stakeholders are, however, considering how to move forward in terms of paying for these expensive new therapies. According to the survey, the most commonly cited payment mechanisms under consideration were outcomes-based deals, cost-sharing agreements and indication-based pricing.

Already there has been some movement in finding new ways to pay for gene therapies. Goudreau pointed to "first of a kind" payment programs in the US for Spark Therapeutics' Luxturna (voretigene neparvovec-rzyl) for treating patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Announced in 2018, these programs involve outcomes-based rebates.

As yet it is unclear which models will prove most popular, Goudreau said. "But it is encouraging that there are several options being considered, scrutinized and evaluated. Some or all of them are likely to evolve, improve and eventually become easier to implement and prove successful over time."

He also highlighted some of the challenges that may arise when implementing these models,

**"It is encouraging that there are several options being considered, scrutinized and evaluated. Some or all of them are likely to evolve, improve and eventually become easier to implement and prove successful over time" – Paul Goudreau**

for example a lack of infrastructure and legal restrictions relating to tracking how drugs are used.

Italy, which is at the forefront in outcomes-based deals and indication-based pricing, is facing problems, Goudreau noted. "Despite having an established system, there still appears to be insufficient evidence to assess whether such agreements have positively impacted healthcare spending in Italy."

He also warned that making product-specific arrangements, administering them and potentially meeting demands for ongoing data collection will place "considerable administrative burden on clinicians, payers and manufacturers, and will have associated costs that will need to be borne." He said that payers may prefer simple approaches instead, such as discounted prices. He also advises companies to consider the relative risks of implementing more complex agreements.

"Specific, appropriate arrangements" must be agreed for each product, Goudreau declared. For example, for outcomes-based deals there needs to be clear agreement on the outcomes that are to be measured and how the data should be gathered.

He also called for more discussion among all stakeholders. "To increase utilization of these innovative pricing mechanisms, there needs to be a consensus and willingness between payers and manufacturers to work together, and with patients, to implement the necessary infrastructure and frameworks to make them work."

# Amgen Joins China Oncology Market Race With \$2.7bn BeiGene Stake

BRIAN YANG



**A**mgen Inc. has an expansion plan and China is a part of it. On 31 October, the major US biotech announced the acquisition of a 20.5% stake in Beijing-based BeiGene Ltd. for \$2.7bn in cash, paying a 36% premium over Nasdaq-listed BeiGene's 30-day volume-weighted share price.

As part of the transaction, BeiGene will commercialize three Amgen products in China including Xgeva/ Prolia (denosumab), which is already approved in the country, and two others - Kyprolis (carfilzomib) and

Blinicyto (blinatumomab) - which are under Phase III development in China. In addition, BeiGene will take charge of China development activities for 20 Amgen preclinical molecules.

All together, BeiGene will set aside \$1.2bn for the development costs of the candidates, which might also include Amgen's KRAS mutation-targeting drug AMG510.

Oncology, along with auto-immune, neurology and cardiovascular, is among the key therapeutic focus areas for Amgen. The China oncology

market continues to grow, driven by favorable regulatory pathways prioritizing new treatments for malignancies along with infectious diseases and rare conditions, and expanded reimbursement coverage for additional cancer drugs.

Propelled by these policy tailwinds, both international and domestic drug makers with large-selling oncology drugs are thriving in the market. Roche has just reported 30% growth in China while AstraZeneca PLC's sales in the country passed the \$3bn mark, driven largely by strong sales of its cancer therapies. (Also see "Second Spring? Coverage Expansion Fuels Big Pharma China Growth But '4+7' Impact Lingers" - *Scrip*, 30 Oct, 2019.)

**"We estimate the China branded market to be \$20-25bn-plus and spending is expected to reach \$35-45bn by 2022"**

Domestic firm Jiangsu Hengrui Medicine Co. Ltd. has also grown to become the first pharma firm with a market capitalization of CNY40bn (\$6bn), helped by a presence in the field.

### Big Boost For Amgen

Through the investment in BeiGene, Amgen could launch some 20 oncology products in China from its pipeline, playing into fast-growing market opportunities, noted analysts at securities firm Jefferies & Co.

Up to now, the US company has launched several new products in China but none in oncology. Its PCSK9 inhibitor Repatha (evolocumab) has gained approval in the country but Amgen believes that its oncology portfolio has large potential there.

Kyprolis has gained both US and EU approval for second-line multiple myeloma with Celgene's Revlimid (lenalidomide) and dexamethasone. "We believe that in order to compete effectively, we need to make investments in the areas and platforms that will position us for long-term success," Amgen

executive vice-president of R&D David Reese said during a 29 October third-quarter earnings call. (Also see "Amgen's Playing To Its R&D Strengths, Which No Longer Include Neuroscience" - *Scrip*, 30 Oct, 2019.)

The oncology potential in China has generated optimism about the overall market. "We estimate the China branded market to be \$20-25bn-plus and spending is expected to reach \$35-45bn by 2022, potentially making China the fourth-largest pharmaceutical market for branded medicines - after the US, Japan and Germany," noted Jefferies in a 31 October note to investors.

### BeiGene Positions Itself As Partner Of Choice

For Beigene, the huge new Amgen deal is a win-win. Although having a solid pipeline of late-stage oncology drugs, including BTK-inhibitor zanubrutinib, PD-1 checkpoint inhibitor tislelizumab and BGB-283, targeting BRAF and KRAS-mutated tumors, the China-focused firm is facing an uphill battle in some areas. Zanubrutinib will compete head on with Janssen Pharmaceutical Cos.'s Ibruvica (ibrutinib), which has also gained local approval.

Competition is also becoming much more pronounced in the PD-1 space in China. Already, there have been five PD-1s approved and launched and more are on the way. With the increasing rivalry, prices for these immuno-oncology products are falling. (Also see "Fifth PD-1, Zavicefta, Novel Psoriasis Ointment Among Latest China Approvals" - *Pink Sheet*, 4 Jun, 2019.)

BeiGene previously teamed up with Celgene Corp. to develop and commercialize its anti-PD-1 molecule, but with the merger of Celgene with

Bristol-Myers Squibb Co., Celgene returned the rights.

BeiGene in early 2018 also signed an exclusive license agreement with Mirati Therapeutics Inc. for the development, manufacturing and commercialization of Mirati's sitravatinib in Asia (excluding Japan), Australia, and New Zealand. Sitravatinib is a broad inhibitor of receptor tyrosine kinases including RET, TAM family receptors (TYRO3, Axl, MER) and split family receptors (VEGFR2, KIT).



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