QMB Innovation Centre

QUEEN MARY BIOENTERPRISES

H2 2020

Discovery

NEWS, VIEWS AND EVENTS AT QMB

IN THIS ISSUE

EDITOR'S WELCOME

Welcome to the winter issue of QMB's Newsletter.

It goes without saying that this has been an extremely challenging year for everyone.

But as difficult as this year has been, we've also seen some of the best that science and innovation has to offer.

At the time of writing, there are around four COVID vaccines that have received approval or are in the process of receiving approval, and a further six in development, all within record time.

Clinical trials are essential to identifying effective treatments and providing understanding about different diseases. We therefore caught up hVIVO, which is developing the world's first human challenge trial for Covid-19.

The study will see healthy volunteers exposed to an attenuated virus as a first step to testing the effectiveness of potential vaccines. In later vaccine trials, volunteers will be given either a new vaccine candidate or a placebo before being exposed to the virus in a controlled setting.

We also caught up with renowned author, Matt Ridley, who is best known for his writing on science, the environment, and economics, and who has written a new book called How Innovation Works.

In a thought-provoking interview, Matt says that even if you have a bright idea, then you need to work out how to make it reliable, affordable and available and that's often very much more difficult than having the idea in the first place.

As an innovation centre that thrives on bright ideas and collaboration, we liked what Matt had to say on the subject.

In other news, Queen Mary has appointed Professor Greg Slabaugh to lead a new Digital Environment Research Institute (DERI) located adjacent to QMB which will drive research innovation across a range of subjects and faculties in line with Queen Mary's long-term growth strategy.

We've also got the latest news from QMB's sister organisation, Queen Mary Innovation, which has just secured two patents based on innovative research at QMUL linked to obesity and osteoarthritis.

We're eager to hear your views too, so please share your feedback in the comments section on our website, or join the conversation on our Twitter page. For more updates and the latest news from QMB, please visit our website.

Nas

Queen Mary set to open additional incubation space in Feb 2021

Queen Mary University of London is set to open additional innovation space offering business development support and infrastructure to help early-stage Digital Health, Med-Tech and AI companies to grow.

Due to open in February 2021, and based within the QMB Innovation Centre, the new space will be called QME (Queen Mary Enterprise) and will be divided into hot desk, co-working and individual offices.

The new space aims to support early-stage start-ups to explore and develop new ventures as well as drive economic growth and enhance health outcomes in Tower Hamlets - England's third most deprived local authority.

Dr Sharon Ellis

"This project is an excellent collaboration between many parts of QMUL, business development, QMB and academic colleagues wanting to commercialise their work and enable others in the local area to do the same," said Dr Sharon Ellis, Director of Research and Business Development at Queen Mary University of London.

"We want to reinvigorate all of QMUL's assets and drive our research and innovation agenda forward in line with QMUL's 2030 Strategy. Our aim is to strengthen collaborative ties between universities and businesses, helping small businesses and start-ups to succeed by providing access to space for them to grow, as well as specialist facilities and expertise," said Ellis.

Right now, demand for incubation space in London far outstrips the supply of available space, creating a bottleneck. QMUL was awarded £1.5 million to expand its life science incubation space in 2020 as part of a £20 million investment into 20 University Enterprise Zones (UEZs) by Research England, which is part of UK Research and Innovation.

Professor Colin Bailey

At the launch, Professor Bailey, the President and Principal of Queen Mary University of London, showed Chris Skidmore, the then Universities Minister, around QMB and the Blizard Institute.

Professor Colin Bailey said: *"This is great news for Queen Mary and our ambitious Barts Life Sciences programme. Our UEZ will bring enormous benefits to London's East End and it demonstrates our enduring engagement with and commitment to our local community."*

Professor David Lee, Deputy Vice Principal for Research (Enterprise), added: *"I am delighted that Queen Mary University of London has been awarded University Enterprise Zone status. The funding allows us to expand our successful QMB Innovation Centre, which is one of the largest and most successful bio-incubators in London. We will be able to support more innovative Life Sciences companies which will help boost the local economy and bring health benefits to people in Tower Hamlets."*

For more information on the space please contact: n.hornett@qmul.ac.uk

Digital Environment Research Institute (DERI) at Whitechapel

Queen Mary University of London has created a Digital Environment Research Institute (DERI) to help drive its research innovation across a range of subjects and faculties.

Professor Greg Slabaugh

QMUL has appointed Professor Greg Slabaugh, who joins from Huawei Technologies Research and Development, where he was Chief Scientist in Computer Vision (EU), to lead DERI and support the delivery of Queen Mary's Strategy 2030.

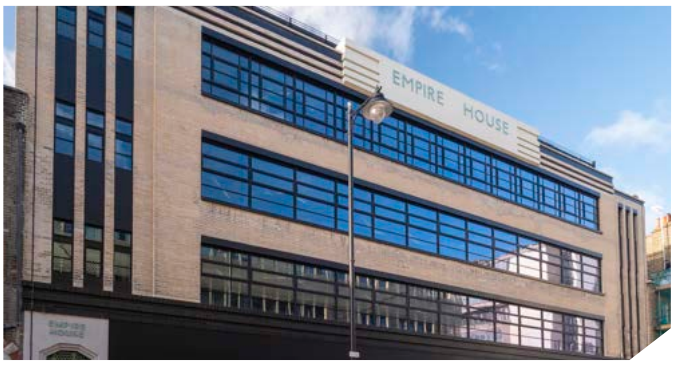
Located adjacent to both QMB and the new Queen Mary Enterprise incubator (QME), DERI will bring together research leaders from humanities and social sciences, medicine and dentistry, and science and engineering.

The new institute will drive new multi-disciplinary research and increase commercial interactions with key businesses, as well as develop existing partnerships with key organisations including Barts NHS Trust and the Turing Institute.

DERI will also help to maintain the UK's leadership in data science and AI by creating and sharing knowledge that drives progress in digital and data science and its applications across a wide range of sectors.

Professor Andrew Livingston, Vice-Principal (Research and Innovation) at Queen Mary said: *"We're delighted that Greg will be joining Queen Mary as Director of DERI. He brings with him a wealth of industry and academic experience, which is essential for driving forward our ambitions for DERI, an integral part of our 2030 strategy that aims to develop a world-class research environment focusing on the University's research strengths in digital and data science."*

Commenting on his appointment, Greg said: *"I'm incredibly excited to take on this role and lead this new initiative that will bring together world-leading researchers from across Queen Mary to deliver innovative multi-disciplinary research. By building new connections between researchers within the Faculties of Science and Engineering, Humanities and Social Sciences and the School of Medicine and Dentistry we have the potential to uncover new research directions and opportunities to advance digital and data science to change our lives and the world around us, for the better."*

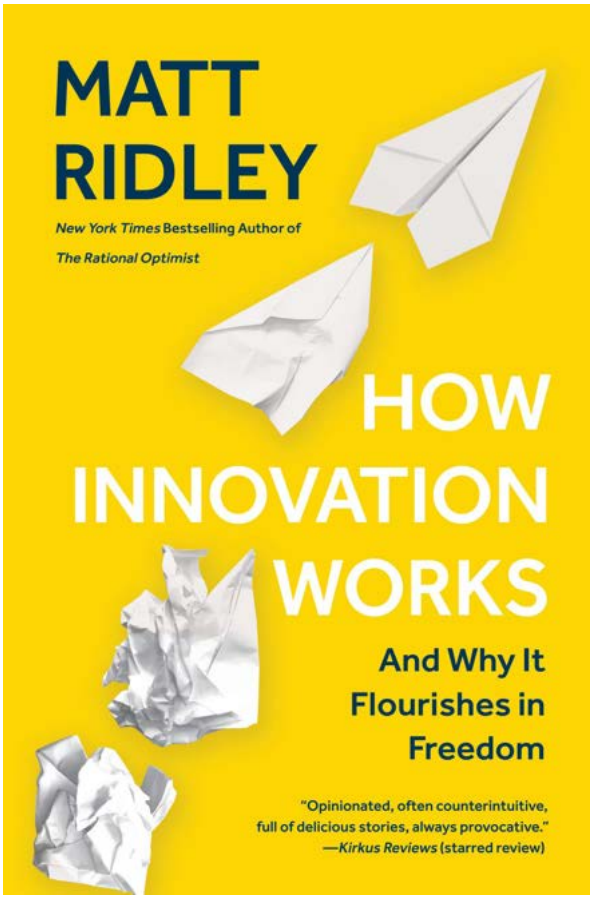


The Big Interview: Matt Ridley

The Innovation Game

Matt Ridley

QMB caught up with Matt Ridley, the author of a new book called How Innovation Works.
In his new book, Matt chronicles the history of innovation, and how we need to change our thinking on the subject. He argues that we need to see innovation as an incremental, bottom-up, fortuitous process that happens as a result of exchanging ideas, rather than an orderly, top-down process developed according to a plan.



You've written about all sorts of innovation over the years but what innovation really excites you and why?

The most momentous innovation was probably the Newcomen steam engine of 1712. This was the first harnessing of heat to do work. Heat and work were separate before that. Wood and coal provided heat; wind, water and oxen did work. Linking the two tapped sources of energy that were eventually highly efficient and almost limitless. The Newcomen engine itself was of limited power and use, but its direct descendants – such as the turbines that give us our electric power today – have proved to be an almost unimaginable boost to human productivity. Or consider a person driving a truck with ten tonnes of cargo at 60mph for 200 miles on a tank of diesel, and then think how much land you would need to grow the hay and wheat to feed the many teams of oxen (and their handlers) to carry a load like that at a far slower pace. In the end, there is a thermodynamic explanation of the world economy and it depends largely on the ability to do efficient work with heat. That process is autocatalytic: it generates a huge energy return on energy invested, which can then be invested in new machinery that generates a further return and so on. This was not possible in the organic, medieval economy.

Who's your favourite innovator and why?

Frederic Darriet. I tracked him down as one of the team that developed the simple low-tech device that has turned the tide on malaria far more than any other intervention: the insecticide treated bednet. He and his colleagues did a series of simple experiments in Burkino Faso in 1983 to show that adding insecticide to a bednet massively deterred mosquitoes, even if the net had holes in it. Malaria mortality was rising until the Gates Foundation adopted this cheap and simple technology: the death toll from malaria has since halved. Yet almost nobody had written up this story, I found, and Darriet was unknown. I contacted him and corresponded with him in my (poor) French, but what I like about this tale is that it reminds us that innovation is not always high tech and does not always make people famous or rich.

Why does innovation matter?

The world has experienced a great enrichment in recent centuries, with poverty dramatically decreased, lifespan hugely lengthened and child mortality greatly reduced. That was caused by innovation and nothing else: not money, not population growth, not resources, not exploitation. It was

new tools and new rules, new ideas and new devices, new ways of using resources, from the internet to corrugated iron, from vaccines to telephones, which made this vast change possible. That's why it matters that we try to understand this process: why it happens at all, why it happens to humans but not to rabbits, why it happens in some places but not in others, why in some industries at some times and in others at other times.

Why is innovation so difficult to achieve?

Innovation is really hard work. Even if you have a bright idea, then you need to work out how to make it reliable, affordable and available and that's often very much more difficult than having the idea in the first place. Thomas Edison tried 6,000 different types of plant material before settling on a kind of Japanese bamboo to use for the filament of his light bulb. Then there's the forces of resistance ranged against innovation: incumbent businesses that don't welcome a challenge; government regulators that employ the precautionary principle to consider only the potential downsides of a new device; and pressure groups that campaign against new technologies, tapping into people's fears. Even coffee when it first reached Europe was subject to frequent and lengthy bans – because the wine and beer industry stirred up fears about its effect on health while rulers grew worried about people discussing sedition in coffee houses. "When a new invention is first propounded," said William Petty in 1662, "in the beginning every man objects and the poor inventor runs the gauntloop of all petulant wits."

How do you ingrain innovation within an organisation?

I don't pretend to have an easy answer to this question. But if you study Amazon, you will find that Jeff Bezos encourages experiment, tolerance of failure, the sharing of ideas, swift decision making, listening to minority ideas, simple hierarchies and bottom-up thinking. These are the kinds of things organisations need. Generally, as they get bigger, both companies and countries/empires get worse at innovation.

We only ever hear about innovations that have been successful, but there must be countless examples of where innovation has failed. Each case will obviously be different, but can we say why a lot of innovations fail?

Failure is natural, inevitable and desirable in innovation. Bezos again: "We need big failures in order to move the needle. If we don't, we're not swinging enough. You really should be swinging hard, and you will fail, but that's okay." Some innovations fail because they are fraudulent or fake: Theranos's blood tests being a recent example, or Delorean's car in the 1970s. Some just don't deliver useful value to the consumer: Google Glass was a technology that worked and was new, but it turned out nobody wanted to buy it for $2000. Some fail because they don't do the hard work of turning an idea into a practical and reliable thing. Edison had 20 rivals who invented light bulbs too but none of them did the immense amounts of trial and error that he did to make it reliable.

What, in your view, are the secrets to innovation?

I wrote a whole book to answer that question! It's not easy to boil down to a sound-bite, but I argue that it's different from invention; it's incremental, collaborative, evolutionary, serendipitous, recombinant, unpredictable and depends on trial and error. These adjectives apply to most successful innovations and yet are largely missing from the way we describe it when devising policy. It is also often the seed of science instead of (or as well as) the fruit.

We have a couple of companies here at QMB that are big advocates of 'open innovation' which, it is argued, is a more distributed, more participatory, and a more decentralised approach to innovation - are you an advocate?

Yes! Procter and Gamble moved to a model of open innovation and it paid dividends – searching for innovations outside the organisation makes a lot more sense than trying to do it in house. A site like Innocentive, where firms can share problems and reward those who come up with solutions, is a great way to achieve open innovation.

What are some of the biggest impediments to innovation?

Priests, chiefs and thieves. That is to say: superstitious arguments against novelty, bureaucratic regulation and breakdowns in the rule of law. Also, I argue that patents are now more of an impediment than a help to innovation: used increasingly as barriers to entry by incumbent businesses. The evidence that the current patent system encourages innovation is actually very weak.

How important are small business incubators like QMB for supporting innovation and inspiring the next generation of innovators?

Vitally important. Small businesses, led by entrepreneurs, are the main authors of innovation. Young people have far too little exposure to the topic of innovation, let alone entrepreneurship and are far more likely to be taught that all commerce is evil than that building a new mousetrap and a new firm to make it, is actually the main way in which human beings do each other favours, by supplying their needs or desires.

Innovate UK is the UK's arm's length innovation agency, which a lot of companies benefit from, including those at QMB, but could we support innovation differently or better to how it's done now?

I am helping to advise the government on innovation policy. In general I advocate clearing the barriers to innovation, rather than subsidising innovators. The latter policy involves picking winners, which often leads to picking losers. To avoid this, where we do use public funds, I think we should do more with prizes, like the Longitude Prize, rewarding innovators for their efforts once they have succeeded. The modern version of this is the advance market commitment where the government offers to buy the product, or to top up the price that can be charged for it, once it is proven to work. For example, the invention of a vaccine against pneumococcus was incentivised by the Gates Foundation with such an advance market commitment.

How will Brexit impact innovation in the UK? What are the opportunities?

The European Union has proved very poor at innovation, as it has often admitted. It produced no digital giants to rival Google, Amazon, Apple or their Chinese equivalents. It has often deliberately prevented innovation, for example with genetically modified and gene edited crops, and in the battle between Dyson's novel bagless vacuum cleaner and its bagged German rivals, where the Commission set rules to help the latter resist the challenge of the former. The precautionary principle, as interpreted by the Lisbon Treaty, effectively argues against doing anything for the first time – by insisting that the potential downsides, but not the potential upsides, of a new technology are considered. It is therefore vital that in leaving the EU, the UK (already by far the most innovative and entrepreneurial economy in Europe) takes the opportunity to reform its policies so as to encourage innovation. If it does so it will not only make its citizens better off, but also safer and healthier.

INTERVIEW

Right now, there's a bottleneck in terms of demand for life science incubation space in London. What can the government do to promote innovation and encourage more scientific / business start-ups?

Free up the planning system – which vastly increases the cost and time of starting a new business and finding somewhere to operate.

What role can QMB and life science incubators play in a COVID-related economic recovery?

In the wake of Covid there will be new emphasis on vaccine preparedness and new diagnostic devices. This is a huge opportunity for an agile school with a strong life science interest. There will also be – sadly – many business casualties of the recession caused by lockdowns. This will create opportunities. And there are new technological habits, especially with online working and conferencing that have become widespread during the pandemic.

Should there be closer ties between the public and private sector when it comes to harnessing innovation?

Not necessarily. The public sector funds a lot of discovery but is not good at the process of turning discoveries into practical innovations of use to consumers. And public sector favouritism can badly mislead entrepreneurs about what it is that consumers want.

Matt Ridley's books have sold over a million copies, been translated into 31 languages and won several awards. His books include The Red Queen, The Origins of Virtue, Genome, Nature via Nurture, Francis Crick, The Rational Optimist and The Evolution of Everything. As Viscount Ridley, he was elected to the House of Lords in February 2013, where he served on the science and technology select committee. He writes a weekly column in The Times (London) and writes regularly for the Wall Street Journal. He is a fellow of the Royal Society of Literature and of the Academy of Medical Sciences, and a foreign honorary member of the American Academy of Arts and Sciences.

QMI Update

Queen Mary Innovation (QMI) Ltd is the wholly-owned technology transfer arm of Queen Mary University of London (QMUL). We caught up with Dr Michele Hill-Perkins, Head of Technology Transfer at QMI's Biopharma Team, to talk about some of the highlights so far this year.

Lower bowel holds secret to weight loss, new research reveals

A human Phase 1 trial led by Dr Madusha Peiris at Queen Mary University London, and supported by Bowel Research UK, has found that specific nutrients delivered to the colon can reduce food intake and be an important tool in tackling the nation's obesity crisis and associated diseases, such as bowel cancer. The double-blind, randomised, placebo-controlled, crossover study was conducted amongst 20 volunteers with a body mass index (BMI) of 30-40kg/m, and investigated the untapped power of the lower bowel to regulate appetite.

The research team found that an active capsule delivering nutrients to the colon could reduce calorific intake. The capsule increased the levels of the appetite-reducing hormone PYY at multiple time points.

Overall calorific intake was found to be significantly less during the active versus placebo treatment, with most of the calorie reduction being at lunch rather than breakfast, and participants did not report any adverse side-effects.


Dr Madusha Peiris

Dr Peiris said: *"With 64% of adults in England classified as overweight or obese, this study could have huge implications for the country's health, including a potential reduction in incidence rates for diseases such as bowel cancer and also the need for obesity surgery."*

Obesity is a key risk factor for bowel cancer, and up to half of bowel cancer diagnoses are related to lifestyle. Obesity can also present considerable treatment challenges in bowel cancer surgery and increases the risk of perioperative complications.

"Our next step is to conduct further trials to assess long-term effect on weight loss and to assess the effectiveness of the treatment on a pre-diabetic population to assess progression to developing type 2 diabetes," said Dr Peiris.

Through QMI, QMUL has patent–protected the unique combination of nutrients that will be marketed as a nutraceutical product.


Dr Michele Hill-Perkins

Dr Michele Hill-Perkins, Head of Technology Transfer at QMI's Biopharma Team, said: *"This is an extremely exciting development, which could transform the way we can prevent diseases associated with obesity."*

Recombinant Agrin for use in cartilage and bone regeneration

QMI has worked with researchers at Queen Mary University of London to file a patent for a novel therapy shown to regenerate defective cartilage and bone.

Professor Francesco Dell'Accio, and co-inventor Dr Suzanne Eldridge, have uncovered a molecule that regenerates bone and cartilage and could potentially play a role in treating osteoarthritis.

Osteoarthritis costs the UK £13 billion a year, when factoring in indirect costs such as carers and being out of employment. The condition causes joints to become painful and stiff and is the most common type of arthritis in the UK, affecting nearly 9 million people.

Cartilage, which overlies bones to enable frictionless movement in joints, often fails to repair after injury which leads to further cartilage loss and osteoarthritis. There is no cure for osteoarthritis, with, current medicine only provide pain management.


Dr Suzanne Eldridge

Dr Eldridge said: *"Many are unable to do basic things, including bathing, getting dressed, cooking or shopping. If we could intervene at an early stage once an injury has occurred, and repair the damage, the likelihood of patients going on to develop osteoarthritis is much slimmer. Our ultimate aim is to transform osteoarthritis from a disease that requires surgery, to one that just requires an injection."*

The team at QMUL studied the effects of a molecule called agrin on animals and discovered that it repairs cartilage by recruiting and activating adult stem cells present in the joint. Their study, published in Science Translational Medicine journal, suggests that supporting such mechanisms is an effective way to help heal injuries that are too big to heal in normal conditions.

Researchers injected mice with a gel containing agrin into "joint surface defects" and after eight weeks found it caused long-lasting regeneration of bone and cartilage – more than a control group that received the gel without agrin.

Testing the agrin-containing gel on sheep also showed cartilage and bone repair was better after six months, when compared to a control group. The sheep spent more time playing and less time resting during the study, suggesting the repair improvement was associated with improved function and pain relief.

Professor Francesco Dell'Accio said: *"We've shown that it's possible to repair joint defects, for the moment at least in animals, not just in the bone but also in the cartilage. One single administration of this molecule is sufficient to trigger a cascade of events in the joints, which, once started, are then self-maintained. Not only does it achieve structural repair, but we've shown that it gives symptomatic relief in animals extremely rapidly."*

Eleftheria Ledaki, Commercialisation Manager at QMI's Biopharma Team, added: *"We are delighted to work with Professor Francesco Dell'Accio and Dr Suzanne Eldridge on securing the patent for this ground-breaking research. We are currently looking for biopharma partners to further develop this technology into an effective therapeutic treatment for osteoarthritis."*

Queen Mary University beefs up Flow Cytometry unit with new analyser instrument

Queen Mary University of London (QMUL) is expanding its Flow Cytometry unit at the Blizard Institute, with the addition of a new analyser instrument.

Flow Cytometry technology is over 50 years old and is used in several applications from immunophenotyping, for example in the detection of tumour markers, and in the diagnosis of leukaemia, to ploidy analysis, to cell counting and GFP expression analysis. Costing up to £421,000, the new machine is due to arrive in the summer following a tendering process.

Cytometers measure cells that span a range of between 0.2 and >50 microns in diameter. As a cell passes through a laser, it will refract or scatter light from all angles. The cytometer measures the forward scatter, or the low angle of light. Fluorochromes bond to monoclonal antibodies bind to cells of interest and the lasers in the flow cytometer excite these fluorophores. The new machine, a Cytek Aurora, can analyse and spectrally un-mix 40 fluorophores by 5 lasers, instead of 14 using the original instrument.

The unit is managed by Gary Warnes, who has worked with the technology for over 30 years, from testing CD4 counts at St. Marys in 1986, to setting up the Diagnostic Lab for CD4 counts at the Immunology Department at St. Thomas' Hospital in 1987.

Gary said: *"The lasers analyse fluorochromes on monoclonal antibodies, which bind to different types of cells inside and out. So, surface CD markers, transcription factors, cell activation markers, cytokines, markers of cell death, DNA and RNA content can also be measured."*

Gary Warnes

QMB tenants Spirogen and ADCT Therapeutics, which are exploring how to effectively use cytotoxic agents connected to antibodies to attack tumour cells, have already expressed an interest in using the new technology.

Gary added: *"Fluorescent DNA dyes can measure the amount of DNA in each cell, so it can be used for the detection of cancer and also determine with the additional use of monoclonal antibodies the different types of leukaemia. Cells can be separated in their millions into test tubes or single cells can be placed into 96 or 384 well Tissue Culture or PCR plates. This enables genomic, proteomics and RNA sequencing to be carried out to great effect in the study of numerous diseases."*

The cell sorter was upgraded in 2012 from version I to III for £75,000 paid from user hourly funds, while two instruments - a BDFACS Canto II 8-colour instrument was installed in 2008, and an ACEA Biosciences Novocyte 3000 13-colour analyser, was bought in 2015.

ADC Therapeutics eyes FDA May 2021 verdict on lymphoma drug LoncaPhil

The US Food and Drug Administration have started a review of ADC Therapeutics' (ADCT) lead drug Lonca for diffuse large B-cell lymphoma (DLBCL), an aggressive form of non-Hodgkin's lymphoma.

Lonca – short for loncastuximab tesirine, and formerly known as ADCT-402 – is an antibody-drug conjugate that combines an antibody against CD19 linked to a cell-killing drug. If approved, it would be a rival to CD19-targeting cell therapies from Novartis (Kymriah) and Gilead Sciences (Yescarta) in the third-line treatment of DLBCL.

QMB tenant ADCT could claim its first product approval in the US as early as next May. The FDA's review will take six-months, with an action date of 21 May next year, and ADCT hopes to have the drug on the market before the end of 2021.

Chief executive Chris Martin said the company has been working on building its salesforce in anticipation of the positive verdict from the FDA, and reckons it can now cover 90% of haematology and oncology specialists who treat DLBCL in the US.

The FDA is reviewing the ADC based on the results of the LOTIS 2 trial. The single-arm, 145-patient trial showed an overall response rate of 48.3% and a complete response rate of 24.1% with Lonca as of a 6 April data cut-off point.

"Based on feedback from physicians on Lonca's efficacy, tolerability protocol and ease of administration, we believe Lonca has the opportunity to become the standard of care in third-line, based on our competitive profile versus other available options," Chris Martin told analysts on a conference call earlier this month.

Chris Martin

ADC Therapeutics is also testing Lonca in earlier lines of therapy. It is running a phase 3 trial (LOTIS 5) of the medicine in combination with rituximab in second-line DLBCL patients, and a phase 1/2 study (LOTIS 3) of Lonca paired with AbbVie/ Johnson & Johnson's Imbruvica (ibrutinib) with relapsed or refractory DLBCL or mantle cell lymphoma (MCL).

The company is also planning to begin a dose finding study of Lonca in combination with R-CHOP chemotherapy in previously untreated DLBCL patients in the first half of 2021, according to Jay Feingold, its chief medical officer.

hVIVO to develop world's first human challenge study for COVID-19

hVIVO is developing the world's first human challenge study for Covid-19, which will see healthy volunteers exposed to the virus in a safe and controlled environment, as a first step towards testing the effectiveness of potential vaccines.

The initial characterisation study is being funded by the Department of Business, Energy, and Industrial Strategy through the Vaccines Taskforce in a deal worth up to £10 million, and is sponsored by Imperial College London.

The study will begin in January at the Royal Free London NHS Foundation Trust specialist facility, involving 50 to 90 participants, pending regulatory and ethical approval.

During the trial, young, healthy volunteers will be exposed to small doses of Covid-19 in a safe and closely monitored setting in the dedicated unit.

Participants in the study will be carefully selected to exclude anyone with a characteristic that has been shown to increase the severity of COVID-19 infection. Volunteer recruitment will commence once ethical approval is received. To sign up to be notified about any potential future COVID-19 challenge studies, visit www.UKCovidChallenge.com

Volunteers will check into a private ensuite for two weeks.

"They get two days to settle in, making themselves at home in a private room with a TV, games console, their phone and other entertainment. Volunteers are served high quality food throughout their stay," said Cathal Friel, Executive Chairman of Open Orphan plc, the parent company of hVIVO.

Two days in, they receive a very small dose of the virus under investigation: in this case, COVID-19, to determine the lowest level at which most people will become infected.

Individuals will be tested for infection via nasal swab tests twice per day, and treated with antivirals, which have been shown in trials to speed up recovery times, as soon as infection is confirmed.

Cathal Friel, Executive Chairman of Open Orphan plc

The study lasts two weeks and volunteers are compensated for their time with a sum set by a UK ethics panel. Volunteers will be monitored for up to a year after the study, to ensure their long-term well-being.

In later vaccine trials, volunteers will be given either a vaccine candidate or a placebo before being exposed to the virus in a safe and controlled setting.

Clinical trials are essential for identifying effective drugs and providing understanding about different diseases.

The prevalence of COVID-19 rises and falls in populations, making it difficult for traditional vaccine trials to assess if vaccines work because those testing the vaccine may not be naturally exposed to it. As Human Challenge Studies deliberately infect the volunteers it is possible for scientists to establish efficacy very quickly.

Human Challenge Studies help in selecting the most effective vaccines by testing them side by side with other vaccine candidates.

Pfizer and BioNTech announced the first interim analysis from the Phase III study of its COVID-19 vaccine candidate, which was found to be up to 90% effective in preventing COVID-19.

More recently, AstraZeneca and Oxford University announced a vaccine, which it believes to be, on average, 70% effective at preventing Covid-19 illness. The US FDA has said any Covid vaccine needs to be at least 50% effective to be useful in fighting the pandemic.

Pfizer expects to produce 50m doses of the vaccine globally in 2020. Britain's medicines regulator, the MHRA, says the jab, which offers up to 95% protection against Covid-19 illness, is safe to be rolled out. There are 10 other vaccine candidates at phase-3 stage.

hVIVO to work with HIC-Vac and the Wellcome Trust to set standards for manufacture of human challenge agents

hVIVO has been selected to lead a consortium tasked with generating regulatory style guidelines on the manufacture of human challenge agents for use in controlled human infection studies.

In doing so it will collaborate with HIC-Vac, an international network of researchers developing human infection challenge studies to accelerate the development of vaccines against pathogens, and the international medical charity, the Wellcome Trust.

hVIVO will help set international standards for challenge agent manufacture and storage, building on the current World Health Organisation guidelines.

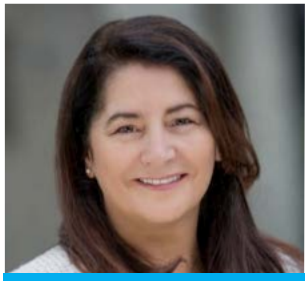
The consortium is also working on guidance fulfilling Good Manufacturing Practice (GMP) requirements for human challenge agents to as much as is practically possible without necessarily being GMP certified. Open Orphan said this will allow flexibility to manufacture challenge agents outside of GMP-certified premises, but with guidance to ensure safety, quality and consistency are maintained.

Learn more about the consortium here.

"We are proud to have been selected to work alongside HIC-Vac and the Wellcome Trust to lead the consortium on these important and much-needed guidelines. hVIVO is at the forefront of human challenge studies and has world-leading capabilities, this collaboration is recognition of the work we do in the scientific community," said Open Orphan Executive Chairman Cathal Friel.

Open Orphan strengthens board with Elaine Sullivan hire

Open Orphan, the parent company of QMB tenant hVIVO, have announced the appointment of Dr Elaine Sullivan as a non-executive director.


Dr Elaine Sullivan

Sullivan is a business leader with senior start-up experience, having been a founder and CEO of Carrick Therapeutics where she helped to raise more than €100 million of investor funds. She is also a senior scientist, holding the role of chief executive at Curadh Pharmaceuticals and a PhD from the University of Edinburgh in molecular virology.

Alongside her non-exec role at Open Orphan, Sullivan is a non-executive director at IP Group and Active Biotech, and a member of the supervisory board of Frankfurt-listed Evotec.

Open Orphan recently announced that non-executive director Mark Warne will step down from its board on the 31 December 2020. Warne had been on the board of hVIVO prior to its acquisition by Open Orphan and assisted with the integration hVIVO into its new owner. He is the last of hVIVO's legacy board members to step down from the company.

Commenting on the appointment, Cathal Friel, the executive chairman of Open Orphan, said:

"We are delighted to announce the appointment of Elaine to the Open Orphan board. Her level of expertise in virology alongside her exceptional career in the industry will be an excellent addition to the Company. We look forward to working closely with Elaine who brings with her a wealth of knowledge and experience and will be invaluable addition to the Company as we now grow Open Orphan substantially in its next phase of rapid development.

Friel added: *"We would like to thank Mark Warne for his service to the Company and for remaining on the Board to allow for a smooth integration of the companies during the transition period following the acquisition of hVIVO."*

NEWS

European biotech raises **$4.8B** in record-breaking quarter

The European Biotech sector enjoyed a record-breaking third quarter, in what is already a record breaking year.

It's no surprise that European biotechnology firms engaged in drug development have been the big winners, raising $4.783 billion in equity financing during the third quarter.

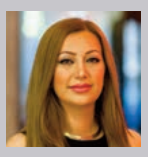
Indeed, if the sector failed to raise one penny more in the fourth quarter, it would still post a new annual record, with European biotechs raising $9.977 billion this year already, well above last year's total of $7.739 billion, which was itself a new high for the sector.

While no European firm completed an IPO during Q1, 10 firms completed IPOs in the last two quarters, six of them in Q3.

Seven of those transactions took place on Nasdaq, while QMB tenant antibody-drug conjugate developer ADC Therapeutics SA took the unusual step of going public on the NYSE. Its $267.7 million raise, completed in Q2, remains the biggest by a European firm so far this year.

Two other IPOs passed the $200 million threshold during Q3. Curevac AG, which has gained global prominence through its development of an mRNA-based vaccine against SARS-CoV-2, took in $245.3 million in August and Gosselies, Belgium-based immuno-oncology specialist Iteos Therapeutics Inc. raised $229.7 million, including the underwriters' option.

PLEASE CONTACT OUR MANAGEMENT TEAM WITH ANY FEEDBACK OR NEWS STORY IDEAS:



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