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Meeting Report

Innovative new pharma and biotech partnerships: How is the landscape transforming? Highlights from the Society for Medicines Research Conference

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Summary

The global pharmaceutical market will be worth more than $1.5 trillion by 2023. This represents an annual growth of 3%-6% over the next 5 years and an attractive area for investment. Challenged with developing the next generation of therapies from purely internal R&D, global pharmaceutical and biotech companies are increasingly looking to form innovative new partnerships to drive portfolio value and growth. Many new investors are also attracted to enter the market from well-established classical CROs, to giant tech companies. With big ambitions and even bigger monetary resources, companies like Amazon, Google, Apple and Microsoft are poised to make significant moves into the global healthcare market, thereby creating an even more diverse ecosystem. Currently, neither traditional pharma nor big tech companies have the full end-to-end capabilities to compete effectively in the future healthcare market alone, which has led to an evident and significant increase in their partnerships. These partnerships aim to exploit the many new scientific breakthroughs, to empower consumers to take control of their own health, to increase development of personalized therapies, to speed up drug discovery and ultimately decrease the healthcare cost at the global level. The 1-day symposium brought together speakers from industry, CROs, not-for-profit organizations and venture capital firms to share their experiences and lessons learned on how these institutions have developed strategies to deal with the evolving collaboration landscapes.

Key words: Pharma – Biotech – Collaborations – Partnerships – Not-for-profit organizations

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Session 1: Approaches to Collaboration in Not-for-profit Organizations

The first session focused on collaborations by not-for-profit organizations. The meeting began with a talk from Graeme Wilkinson, Head of Virtual R&D, Catapult-Medicines Discovery (MDC), who presented on "The challenges and opportunities for collaboration in a not-for-profit organization". MDC, part of the Catapult network, was established by Innovate UK in 2015 as an independent, not-for-profit organization. Research labs were opened at Alderley Park 3 years later, and it currently employs over 130 staff, many with industry experience.

The overall aims of MDC were described, i.e., to support SMEs and other innovators to deliver growth for the drug discovery industry, to connect the drug discovery community (including academics and spinouts), address the industry challenges that limit progress and drive the uptake of new approaches for discovery of new medicines. An overview was presented of MDC's capabilities, which encompass cell models, biomarkers and translational aspects, target and pathway engagement and aspects of drug delivery and biodistribution. These together with consultancy expertise are brought together to address the common challenges

facing the drug discovery sector, which include those which affect "individual innovators" (e.g., no access to industry skills) and the wider sector (e.g., lack of connectivity in the U.K. life sciences sector). MDC is focused on providing solutions to some of these challenges.

Graeme went on to describe the advantages of collaborating in drug discovery (e.g., sharing costs, risk reduction), and the role a "not-for-profit", such as MDC, can play in such collaborations. Apart from management and scientific roles, its role as an "honest broker" was highlighted in the so-called innovation journey from the innovative idea, through spin-out, investment (Series A, B) and ultimately hitting a value inflection point (e.g., acquisition, licensing deal, etc.). The nuts and bolts of the MDC process were covered by Graeme, giving potential collaborators a clear insight as to what to expect and how they would work with MDC.

The presentation was rounded off with a description of MDC's successes. These included the Psychiatry Consortium, a pre-competitive consortium of charities and pharma with the aim of accelerating drug discovery in psychiatric disease; the development of the UK Cystic Fibrosis Infection Biorepository, whose aim is to allow researchers to access high-quality and clinically relevant tissue samples, data and experts to accelerate development of treatments for cystic fibrosis; supporting the creation of new oncology-focused companies ("Oncology Accelerator"), through collaboration with pharma (GSK, AZ, Roche, J&J), NHS Christie Hospital, Cancer Research UK and others; and the PET Network, aimed at creating a national infrastructure that supports the needs of basic, clinical and industrial research.

The second talk of the session was given by Andy Merritt (LifeArc, U.K.) on "New strategies for early translation; the LifeArc vision for 2030". LifeArc, formerly the MRC Technology group, was established in 2000, and are "early-stage translational specialists". Its aim is to bridge the gap between the laboratory and the patient, by advancing early scientific discoveries to a point where they can be developed into new therapies and diagnostics. It has 4 labs across the U.K., and currently employs over 200 employees, all with expertise in drug discovery. It has over £1 billion of resources committed until 2030, due in great part to royalty income from the success of the cancer drug Keytruda (pembrolizumab).

LifeArc focuses on 3 areas of translational science—providing translational advice (e.g., on technology, IP), prosecuting translational studies in its own laboratories and in providing funding to fill gaps in the "translational journey" for promising ideas. It is committing £1.3 billion to early-stage projects to develop new treatments. This is structured around a framework of 3 strategic pillars. The first, "Impact with Partners" focuses on creating greater access for science innovators to expertise and funding and scoping out areas where LifeArc can have the greatest impact for patients. The "Early Ventures" pillar provides investment to bridge the gap between academic innovation and mainstream venture funding. Finally, "Translational Challenges" are long-term programs around specific disease areas, themes or health needs. These will involve several partners (e.g., charities, centers of excellence) to solve complex challenges. It is expected that 3 such challenges will be initiated by 2023, each with a budget of up to £100M! Ambitious goals have been set for LifeArc with the aim of establishing 6 translational challenges and between 10 and 15 new early investments made by 2030.

Andy concluded by describing the MND Translation Challenge as an example of LifeArc's activity. There are currently no treatments for motor neuron disease (MND), a fatal neurodegenerative disease. LifeArc has identified several areas where it can impact on developing potential therapies. These include developing more effective techniques for the early diagnosis of MND; developing new disease-modifying treatments and devices to improve the quality of life of MND patients; and in gaining a better understanding of pathophysiology of the disease. Various activities have already started, e.g., a major award (£4.25M) to initiate U.K. collaborative research initiative with MND charities, MRC and NIHR

Session 2: Drug Discovery Collaborations in Biotech and Pharma

In the first talk of the session, Peter Atkinson (Eisai Therapeutics, U.K.) discussed "Collaborative models to promote innovation in neurology drug discovery". Eisai is focused on developing medicines for the treatment of dementia and other neurodegenerative diseases and sees this as a collaborative and cumulative effort through external innovation. Partnerships with academic institutions, nonprofit organizations or other companies are actively pursued, to find new therapeutic approaches that will ultimately meet the needs of patients. The Neurology Innovation Team at Eisai is central to establishing partnerships in neurology. The overall aim is to share knowledge, resources and expertise to achieve "mutually beneficial outcomes". There is a particular focus on new targets, enabling technologies and concepts that are built on human disease-based evidence (e.g., pathological or genetic data) with good translational potential. They have a broad remit in terms of project scope. This includes the identification and validation of novel targets and pathways, translational biomarkers and next-generation technologies. Projects are within the neurodegeneration field, with mutually beneficial aims for Eisai and its partners.

The Eisai team encourages a flexible approach to collaboration which can be tailored to the specific needs of the joint project. These are typically operationally managed through a Therapeutic Innovation Group (TIG) and overseen by the collaboration's Joint Steering Committee. Although the contribution from Eisai can vary according to the challenges faced, Eisai believes that the working model allows for the formation of true scientific alliances, with its scientists providing intellectual input to joint project teams, while

enabling collaborators to access Eisai's in-house drug discovery expertise and capabilities.

In the last 10 years, Eisai has established a broad range of partners. These include a long-standing collaboration with UCL. It is also part of the Milner Therapeutics Consortium with Cambridge University, the Sanger and Brabraham Institutes and 10 other pharma companies. It is a key member of ALBORADA Drug Discovery Institute, a group of 3 research institutes at Cambridge, Oxford and UCL working in partnership with industry to develop novel therapeutics of Alzheimer's disease. In addition, to further support emerging targets and therapeutics, Eisai has established a venture investment arm as well as establishing the Eisai Innovation Center in 2021 in Cambridge, Massachusetts.

Fiona MacLaughlin (Johnson and Johnson Innovation, U.K.) spoke on "The role of external innovation for pharma: the power & shape of meaningful collaborations". The overall goal of J&J Innovation is to produce a "differentiated product", and to do this she indicated that it required transformative innovation. To drive this, J&J Innovation has committed to a 5-year spend of $325M. So far it has made nearly 50 investments, with 7 being "on-boarded" to the company. The investments range from seed funding through Series A to C, to incubator and accelerator organizations and "NewCo" creation.

She then went on to describe the current trends in the external innovation ecosystem. The COVID pandemic appeared to increase R&D funding. However, deal making remains "muted, with a reduction in mergers and acquisitions, and a move towards partnerships and on early-stage assets."

Fiona concluded by describing various deals J&J had established, including those with Ligan Biotech (CAR-T therapy), MeiraGTx (clinical-stage gene therapy), Mesteg Therapeutics (fibroblast-based therapies) and various consortia and private/public partnerships, each with its own deal structure. Finally, an interesting point made in the Q&A was the challenges facing platform technologies on providing an ROI for investors. The better option is to focus on a single asset and not the platform.

Richard Mason (Apollo Therapeutics, U.K.) talked about "Building a next generation of biopharma". Apollo is a drug development company, established in 2016, as a joint venture between Imperial College, University College, King's College and the University of Cambridge with support from AstraZeneca, GlaxoSmithKline and Johnson & Johnson (J&J Innovation). The tech transfer units at the universities provided around £3.5M ($4.7 million), with pharma providing £10M each. At the beginning of this year, Apollo raised a further £160M investment from U.K. and U.S. investors.

The company follows a portfolio-based model, sourcing innovation and drug discovery projects from the 4 universities and bringing them forward in "the most capital and time-efficient way possible." Apollo supports its R&D efforts with a centralized, industry-experienced team and resources in Cambridge (U.K.) and Boston (U.S.), allowing it to shift staff and funding between the different assets as needed. Its core area of focus is in immunology, cell stress and metabolism and cell signaling, in which it has nearly 20 active projects. These are mechanistic drug targets, and are disease agnostic.

Richard stressed the importance of the portfolio model for R&D in drug discovery. This describes the approach taken both by pharma and venture capital (VC) organizations. However, both organizations experience their own challenges, e.g., lack of agility, high fixed costs, focus on defined therapeutic areas in pharma; VC-backed companies may lack effective management, difficulty in prosecuting the "killer experiments"; and VCs can duplicate management and investment across companies in their investment portfolio. The Apollo model seeks to address these disadvantages through centralized scientific portfolio management by its industry-experienced team, efficient use of its capital, and approach characterized by starting with the end in mind, i.e., what is needed to get an asset to the market. In the Q&A session, Richard was asked if Apollo would be listed. He thought this might be necessary to get an asset to market, given the costs of drug development.

Adam Stoten (Evotec, U.K.) presented on "Harnessing academic innovations; the need for industrialisation". Evotec, with its robust platform of expertise and capabilities encompassing drug discovery and development from target ID and validation to clinical development, has established an extensive network of > 500 partners (including pharma/biotech, academia and foundations). The academic sector is a rich source of drug approvals, but successful translation of projects from universities to industry is challenging. Leveraging and coupling its resources with academic opportunities, Evotec has developed the "bridge model", defined as a strategic partnership with academia, industrial partners and funders to accelerate translation. The model aims to develop the assets from academic concepts to an investable stage, i.e., "NewCos" such as Dark Blue Therapeutics, or licensable assets. Oxford Bridge "LAB282", an exemplar bridge underpinned by intellectual property from the University of Oxford in collaboration with OSI, has facilitated > 12 successful projects and potentially 3-6 NewCos. These projects have encompassed a broad therapeutic area encompassing, but not limited to, oncology, neurology and inflammation. Dark Blue Therapeutics was established with the aim of developing IP from the University of Oxford to a portfolio of medicines targeting disparate areas of cancer biology. Expanding the paradigm further was exemplified by beLAB2122, a partnership between a number of German Universities and BMS. Significant growth and expansion of the bridge model are anticipated beyond 2022. Challenges that were met were summarized and included

administrative barriers, e.g., tax; the original budget set for reaching in vivo proof-of-concept stage was insufficient and maintaining focus of the PIs. In summary, the bridge model, by harnessing academic opportunities and accelerating its translation, has enabled the creation of a NewCo and over 75 first-in-class projects, with pre-agreed terms of equity and revenue for Evotec.

Session 3: How Is the Collaborative Landscape Transforming?

In the final talk of the day, Daniel Marshall (MSD U.K.) talked about the Merck partnering strategy and some selected deals in his talk entitled, "The evolving biopharma deal landscape in 2022". In 2021, over half of Merck's revenue from its human health business was attributed to products obtained from licensing or acquisitions, including Keytruda and Gardasil, highlighting the importance of external innovation to the overall portfolio. The business development strategy covers 5 primary therapy areas—cardio-renal/metabolic/ophthalmic, infectious disease, immunology, neuroscience and oncology—and focuses on identifying strong science and emerging biology as primary drivers. The team is also agnostic to therapeutic modality and pursues programs in cell and gene therapies, small molecules, biologics and oligonucleotides. Ultimately, products need to deliver clear and promotable advantages over existing therapies, rather than differentiation through improved safety alone. The business development team is based out of 4 hub sites—Kenilworth (HQ), Boston (EC hub), San Francisco (WC/Pacific hub) and London (EU hub).

Daniel went on to discuss some recent deals in the oncology area which were done to continue Merck's leadership position in this therapy area. These included Merck's $394M acquisition of Viralytics in 2018 to gain access to an investigational intra-tumoral and intravenous formulation of the coxsackievirus type A21, designed to infect and kill cancer cells; the 2019 acquisition of Peloton Therapeutics for $1.05B to develop novel small molecules targeting HIF-2α for the treatment of patients with cancer and other diseases; and in 2020, a collaboration with Seagen was initiated to develop ladiratuzumab vedotin as both a monotherapy and in combination with Keytruda for the treatment of breast cancer and other LIV-1-expressing solid tumors. In the preclinical phase, several partnerships were discussed, including with Tilos for a portfolio of investigational antibodies modulating the TGF-β complex and Astex for the development of small-molecule inhibitors against several drug targets, including the KRAS oncogene.

Panel Discussion

The day concluded with a panel discussion, featuring all the speakers, and moderated by Sam Fizeli (Bloomberg Intelligence). From this interactive discussion, several important points were highlighted. These included:

- M&A activity is down.
- It is cheaper to acquire an (early-stage) company than do an in-licensing deal!
- "Enablers" are needed, i.e., organizations that can support and facilitate the interactions between small spin-outs, academic groups, funders and pharma.
- The "Hollywood Model" can be applied to external innovation. The approach applies the business method for how modern movies are made. You create a team that temporarily works on a project with the timelines dependent on the scope and budget of the work. The model is easily adaptable, and investment can be reassessed constantly.

Conclusions

This was an excellent meeting, which brought together scientists from a range of organizations focused on discovering and developing new therapeutics through partnership and collaboration. It was evident from the presentations and panel discussion that the landscape and opportunity for partnerships are changing and a variety of approaches and opportunities now exist. Their successful implementation and outcomes will achieve the key goal—to bring forward new medicines for the benefit of patients.

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