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ASIA EDITION

Ã¢â?¬Å?An efficient approach to clinical trial design will have the greatest impactÃ¢â?¬Â•

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Dr John Moller joined Novotech in January 2014 to lead the development of Novotech's Asia operations.



The annual J.P. Morgan Healthcare Conference is the premier investor conference focused exclusively on companies defining the healthcare industry. This is the largest and most informative healthcare investment symposium in the industry, bringing together industry leaders, emerging fast-growth companies, innovative technology creators, and members of the investment community. The annual event draws more than 450 companies, both public and private, and more than 10,000 attendees. At the recently concluded 37th Annual J.P.Morgan Healthcare Conference from 7 -10 January 2019, Novotech CRO was invited to share the advantages of conducting clinical trials in Asia-Pacific. Dr John Moller, CEO, Novotech interacted with BioSpectrum Asia to share his views on the 2019 catalysts in the clinical environment.

Edited Excerpts:

Could you tell us a bit more about your views on 2018 and the biotech landscape for 2019?

In the past year we've observed an unprecedented level of innovation, with 55 new drugs or biologics approved by the FDA (the highest number since the mid-90s), including the approval of new drug classes.

As innovation continues to accelerate, so do development costs, and drug pricing will remain a key topic this year which might create tradeoffs for big pharma between dividends, M&A and R&D expenditure. In the US, pricing is increasingly a bipartisan issue and we are starting to see innovative models being proposed to address these issues. For example, Bluebird Bio is proposing a creative system of payment-by-installment based on continued efficacy of its gene-replacement therapy LentiGlobin for beta thalassemia.

Capital raise is a key challenge for biotech companies. How do you see this having an impact on research in the current period of economic uncertainty?

2019 is kicking off strongly in terms of M&A with Celgene's acquisition by BMS for a record $74 billion and Eli Lilly's $8 billion buyout of Loxo Oncology. We might be looking for a solid year in terms of M&A with large pharmas looking more than ever to strengthen their drug pipeline. Although the public biotech markets are currently going through a period of volatility, the fact that healthcare remains a less cyclical sector makes it a strong area of focus for investors. In fact, IPO activity picked up substantially in 2018 along with record equity financings, which totaled over $64 billion over the year. This will inevitably fuel more research, and biotechs are increasingly looking at cost effective locations such as Australia, that will take their research further, reducing the need for dilutive capital raisings.

What sense do you get of the challenges biopharma companies face now in the CRO space and how is Novotech effectively addressing these issues?

From a recent survey conducted by J.P. Morgan amongst life sciences investors, clinical data quality is considered the key priority for 2019. This is especially true given the increasing complexity of trials and trial designs. We see an increasing investment in upfront clinical development strategy, including the use of carefully designed protocols. These include multi-arm, multi-stage design and adaptive randomization. In our view, an efficient approach to clinical trial design will have the greatest impact in containing the escalating cost of drug development.

The effectiveness of clinical trials relies on the selection of the right investigators, and how CROs manage study operations. Novotech invests heavily in building formal partnerships with major hospital and medical specialist sites through formal site partnership agreements, as well as in site management services which facilitate rapid start-up activities and patient recruitment to meet the sponsor's goals.

What changes do you observe in Asia-Pacific and how is the region now positioned in the global clinical trial landscape?

With biotech companies investing in more complex and global programs, and with many talking about structuring themselves to take their drug "the whole way", we see biotech sponsors increasingly considering locations outside of the US for their trials, such as Eastern Europe and Asia-Pacific. Novotech clinical staff numbers have grown by more than 20% in Asia over the last quarter of 2018, fueled by demand for a regional CRO with international accreditation and reputation, combined with local knowledge, partnerships and expertise in the region.

In Australia, recent tax policy amendments have reinforced the country's commitment to the R&D expense refund scheme particularly in relation to clinical trials. Biotechs consider the scheme to be one of the most supportive in the world which drives many of them to run their early phase trials there. The US government shut down is interestingly pushing a number of biotechs to consider Australia more seriously, as they are concerned about the impact on FDA review timings. Furthermore, we increasingly see biotech companies taking advantage of the Australian market to run their first-in-human studies and then look to including sites in Asia to accelerate the next phases of their programs.

While there are many benefits in running clinical trials in Asia, sponsors can often face fragmented markets and heterogeneous regulatory pathways, standards of care and cultures. This reinforces the need for them to partner with a regional specialist with a deep understanding of these market nuances and with on the ground presence in each country. The key challenge for small and medium sized biotech companies is to run their early phase trials in an environment promoting simple and predictable regulatory pathways, while planning their later phase research.

Novotech completed its first-ever acquisition in 2018 of Australia specialist CNS. How will this serve Novotech and its clients?

This acquisition has further strengthened Novotech's presence in the region, and has allowed us to offer all clients the CNS 'BioDesk,' that provides early stage product development advice including toxicology, CMC and FDA/EMA regulatory consulting. With increasing investment in upfront clinical development strategy, including the use of carefully designed innovative protocols, the integration of capabilities such as BioDesk will bring tremendous support to biotech companies looking for global regulatory services.