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January 07, 2016 07:00 ET

Clinical Trial Planning in Asia: A Roadmap for Biotech Sponsors, Upcoming Webinar Hosted by Xtalks

TORONTO, ON--(Marketwired - January 07, 2016) - Join industry experts from Novotech including John Moller, Chief Operating Officer (Asia), Kim Wong, Head of Regulatory Affairs, and Betty Li, Head of Operations (Greater China), for an informative live session on Friday, January 22, 2016 at 11am EST (4pm GMT).

As with many other industries, there is a prevailing belief that the 21st Century will be the Asian Century when it comes to drug development and the pharmaceutical industry. Already, markets such as China are predicted to overtake the US to become the largest pharmaceutical market in the world during the first half of this century. As the globalization of clinical research gathers pace, the Asian region will continue to grow making it the most exciting frontier for biotechnology and pharmaceutical companies to conduct clinical research in. In a recent Novotech survey of executives from biopharmaceutical companies, 98% of respondents said they would consider the Asia Pacific region for future clinical trials.

Home to 60% of the world's population, Asia's popularity for clinical research and development has been fueled by four key factors:

1. Cost-effectiveness and time efficiencies afforded by large populations, significant numbers of treatment naïve patients and high urban densities
2. A wide range of chronic and lifestyle disease patterns driven by rising prosperity and aging populations
3. Increasingly robust and efficient regulatory and ethics processes
4. Quality improvements resulting from massive investments in research infrastructure and human resources

Access to Patients

In the last two decades, the total universe of clinical trials has not only greatly increased in number but become far more complex. The twin factors of increasing volume and greater complexity are at least as important as cost considerations when assessing the Asian century in the context of the clinical trials. Far more people, and far more patients, live in Asia than any other continent. Combined with a relatively low base of clinical

trials historically in the region, it is not difficult to see why Asia is of such importance to the pharmaceutical industry. Led predominantly by US-based biotechnology companies, the region is now also increasingly popular for biotechnology sponsored phase II and III clinical trials. This trend is likely to gather momentum, with the key being greater access to patients. In many therapeutic areas, the patient demographics and disease prevalence is comparable across the world, and this weighs heavily on the decision where to conduct larger pivotal studies. The factors influencing such decisions are largely the same for both pharmaceutical and biotechnology companies.

Regulatory Considerations

With the widespread adoption of the international Good Clinical Practice guidelines around the world, regulatory hurdles around data acceptability for clinical trials conducted in emerging markets have been steadily coming down. Indeed a recent report by the European Medicines Agency (EMA) indicated that more than a quarter of all patients enrolled in pivotal trials that were submitted to the Agency during the period 2005-2011 came from the rest of the world (ROW) represented predominantly by Asia and Latin America. Of greater interest is that this trend is increasing. So, whilst only 20% of all patients came from ROW in 2005, this number had risen to 37% in 2011 (Ref. Clinical trials Submitted in Marketing Authorization Applications to the European Medicines Agency - April 2013).

Infrastructure and Government Support

Fueled by the continued interest, governments in Asian countries increasingly view biomedical/life sciences industry as a key segment for future economic growth. Substantial financial support has been granted to this segment resulting in improved clinical research infrastructure in many of the region's countries. Another important reason for Asia's growing demand is the availability of world class medical professionals and investigators. Economic and political factors, such as trade agreements between countries, also have an impact on easing trial registration and timelines, thus affecting trial numbers. For example, Japan, South Korea, and the People's Republic of China have established a tripartite partnership, with a common regulatory body in the works, in recognition of their ethnic, genetic, and economic similarities. However, as attractive as the Asia may be, navigating the maze of trial logistics, local regulations and cultural differences can present major challenges. To conduct clinical research in Asia, it is therefore very important to work with a partner with local expertise and capabilities on the ground.

For more information or to register for this free webinar visit: Clinical Trial Planning in Asia: A Roadmap for Biotech Sponsors

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