



PRESS RELEASE

Clinical Network Services (CNS) signs cooperative agreement with BD Consultancy

Additional developments include:

- ***Dr Richard Turner joins the team to undertake technical leadership of the UK office.***
- ***UK office granted SME status by the EMA***

Brisbane, Australia- 3 November 2014 - Clinical Network Services (CNS) an integrated product development company based in Australia and New Zealand providing broad services in the planning, implementation and delivery of preclinical, Phase 1 and 2 trials, and Biologics Development Consultancy B.V. (BDC), a team of consultants providing regulatory and product development advice on the development and commercial production of biotechnological, biological and drug products, today announced that they have signed a cooperative partnership agreement where CNS, and in particular the BioDesk consultancy, and BDC will mutually expand the expertise they can together offer their clients.

Cofounders of BD Consultancy, Dr Bertjan Ziere and Dr Erik Doevendans commented:

"We see tremendous opportunities through this collaborative partnership as there is scope for significant synergies that will provide mutual benefits to clients of both consultancies."

Dr Richard Turner will at the same time join the London team as Principal Consultant, assuming technical leadership of the UK office. Dr Turner is a former pharmaceutical and scientific assessor at the Medicines Control Agency (now the known as the UK MHRA). He joins CNS from Daiichi Sankyo where he was Director of Regulatory Affairs and has also worked in senior regulatory roles at Lonza Biologics, ERA Consulting, Elan and Antisoma. He has a PhD in Microbial Chemistry and started his career as a research scientist at Delta Biotechnology.

Mark Reid, Director BioDesk & Regulatory Affairs commented:

"The partnership with BDC is a very strong signal to our market that CNS continues to build a world class regulatory and preclinical consulting service and to have access to the renowned expertise that Bertjan and Erik have will be of great benefit to our clients through the early stage development of their products. I am particularly excited that we are also able to combine the BDC expertise with our own appointment of Dr Richard Turner as a Principal Consultant."

In further news CNS also announced that the European Commission and the centralized European Medicines Agency (EMA) has recently granted SME (Small and Medium Sized Enterprise) Status to CNS. The EMA originally launched the designation of "SME Office" on 15 December 2005 based on European Commission Regulation (EC) No 2049/2005 focused on providing financial and administrative support to small and medium sized enterprises. This initiative was developed to promote innovation and encourage the development of new products by SMEs.

Paul Cronin, Director CNS UK and Business Development at CNS commented:

"Achieving SME status in Europe is a significant milestone and the progress we have made in developing the UK business in only a few months is deeply pleasing. Wonderful to welcome Richard Turner, a former UK regulator, to the team as well as working more closely with the team at BDC and their background as assessors at the Dutch MEB and numerous other senior management roles in European Biotech."

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About Clinical Network Services

Clinical Network Services (CNS) Pty Ltd is an Australian, New Zealand and UK CRO offering integrated development services to virtual, small and medium sized Biotech companies in the planning, implementation and delivery of Phase 1 and 2 trials, and beyond. CNS offers a unique service where it integrates **BioDesk**, an intelligent product development planning and regulatory affairs service, with our committed, highly experienced regional clinical operations team. The CNS "Regional Advantage" is driven by our extremely pragmatic regulatory environment that makes it possible for our clients to enter the clinic quickly, without the need for prior regulatory agency approval. Specifically, **BioDesk** works closely with our clients to design, implement and manage manufacturing and preclinical plans that are mindful of commercial timelines and budgets, allowing swifter go/no go decisions for our clients and their investors. With operations across Australia and New Zealand, CNS makes use of its close relationships with key opinion leaders, world leading clinical facilities, and globally respected Phase I units across a wide variety of therapeutic indications. Our service offerings include: product development, regulatory affairs planning and development, clinical planning, study start up, monitoring, project management, data management, biostatistics, pharmacometrics, medical consultancy/monitoring, medical writing, bioanalytical services and safety reporting.

Further information on CNS can be found at www.clinical.net.au

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Notes for editors

About BioDesk

BioDesk is a unique global product development and regulatory planning consultancy which assists Biotech companies get into the clinic faster through creating and managing a manufacturing and pre-clinical programme that encompasses a globalised regulatory perspective whilst leveraging unique regional advantages.

Specifically, BioDesk works closely with our clients to design, implement and manage manufacturing and pre-clinical plans mindful of commercial timelines and budgets, allowing swifter go/no go decisions for our clients and their investors.

Services offered by BioDesk include:

- Developing a forward looking Product (Drug) Development Plan
- Supporting the aggregation of pre-clinical chemistry, GMP and CMC
- Formulating development plans appropriate to venture capitalists and regulators
- Strategic regulatory advice for key international and local markets
- Support and development of regulatory submissions such as INDs, CTAs, BLAs, MLAs, etc.
- Project and programme management.

Through BioDesk, CNS offers the Biotech industry a focused approach to biotherapeutic development. When coupled with our clinical management expertise, our approach drives efficient navigation through the critical period of post-discovery planning and initial clinic testing whilst adding value to the global dossier and delivering improved commercial outcomes to our clients.