Clinical Network Services (CNS) Expands its BioDesk Service into Washington D.C.

Dr Bryan Smith appointed Principal Medical Consultant and Sally Yang as Regulatory Consultant

Brisbane, Australia - 6 January 2016 - Clinical Network Services (CNS), an integrated service group focused on clinical product development and headquartered in Australia with offices in New Zealand, the UK and the USA, has announced that it has established a new office on the East coast of the USA for its expanded BioDesk division.

With CNS already established in the USA in San Francisco, the expansion of a BioDesk office in Washington D.C. extends the consultancy's US footprint, building on product development and regulatory consultancy services offered in Australia and Europe. It will enable BioDesk to better support its clients seeking to engage with the FDA.

Dr Bryan Smith, who recently joined Clinical Network Services (USA), Inc. as a Principal Medical Consultant, will lead the Washington D.C. team. Dr Smith, a Family Medicine Clinician and Clinical Pharmacologist, has most recently served with the US Army Medical Materiel Development Activity (USAMMDA) where he chaired the multidisciplinary Integrated Product Teams and managed the development of products designed to prevent and treat malaria in the US Armed Forces. Previously, Dr Smith was a Fellow with the Walter Reed Army Institute of Research (WRAIR) Experimental Therapeutics, Dept. of Clinical Pharmacology and Assistant Chief, Department of Immunology and Medicine, Armed Forces Institute of Medical Sciences, in Bangkok, Thailand.

In addition, Sally Yang will be joining Dr Smith in the Washington D.C. office as a Regulatory Consultant. Ms Yang has a strong background of interacting with the US FDA and in particular orphan drugs.

Mark Reid, Director of BioDesk and Regulatory Affairs commented: "Having worked closely with Bryan for several years I am confident that our successful relationship will continue as Dr Smith establishes BioDesk on the US East coast. Our talented team in the US complements the very successful team we have in the UK and across Australia. Sally and Bryan make an ideal start-up team and I look forward to growing that team over the coming period" he added.

Commenting on the expansion and the global success of CNS, Russell Neal, Managing Director said: "CNS' reputation for value-adding expertise and services in very early stage product development has grown tremendously over the last few years. To be able to include the US in our geographical capabilities means we now cover the major regulatory authorities.

"It has always been our ambition to provide small biotech/biopharma companies a real alternative to the larger consultancies whilst at the same time offering a broad and deep range of services that smaller organisations struggle to fulfil internally. The synergy between BioDesk's global regulatory and development planning capability combined with our ability to provide the substantial benefits offered by our Australian/New Zealand early phase clinical services, is increasingly attractive to our global client base" he said.

CNS has experience on almost 400 distinct projects across 28 therapeutic areas and 105 indications. The BioDesk team, specifically, have worked on over 150 projects with particular development expertise in vaccines, stem cell therapy and gene therapy.

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About Clinical Network Services

Clinical Network Services (CNS) is an integrated service group focused on product development headquartered in Australia with offices in New Zealand, the UK and the USA, who create value for small-medium sized biotechnology companies by progressing early stage products through phase 1 & 2 clinical trials or the marketplace sooner. CNS offers a unique service where it integrates BioDesk, an intelligent global product development and regulatory affairs consultancy, with our committed, highly experienced Australian/New Zealand clinical services and biometrics team. CNS' regional clinical advantage is driven by the extremely pragmatic regulatory environment in Australia and New Zealand that makes it possible for clients to enter the clinic quickly, without prior regulatory approval.

CNS offers a uniquely differentiated, customer-orientated, suite of services to clients which enables CNS to guide products efficiently through critical post-discovery development and into initial human trials. Throughout, CNS takes a global development/ regulatory strategic approach to ensure that value is added at every stage of the product development life cycle.

Further information about CNS and its intelligent development services can be found at
www.clinical.net.au

About BioDesk:

CNS' BioDesk is an expert consulting team offering CMC/manufacturing, toxicology, clinical and regulatory affairs consulting services for readying products to enter clinical trials or marketing approval.
The BioDesk team consists of experienced chemists, toxicologists, medical writers, regulatory affairs specialists and experienced clinicians based in Australia, Europe and the USA. BioDesk works closely with clients to design and implement manufacturing operations and non-clinical plans, mindful of commercial timelines and budgets. BioDesk further adds value by ensuring that a global regulatory standard is inherent within client development programs. After submission of a marketing approval, BioDesk collaboratively works with the experienced Australian/New Zealand clinical operations and biometrics teams to realise client goals.

BioDesk core services include:

- Developing clinical development plans and drug development plans - starting with the end in mind.
- Getting client GMP-compliant clinical trial material ready for the clinic.
- Completing client GLP- compliant toxicology studies before human studies start.
- Arranging meetings with the regulators and helping clients ask optimal questions in order to elicit helpful responses.
- Writing up all applications for the regulators including big or small projects: orphan applications, paediatric investigational plans, to New Drug Applications and everything in between.
- Providing medical writers to write up protocols, investigator brochures and all modules in the Common Technical Dossier required for a marketing application.

Further information about BioDesk services can be found at
www.cnsbiodesk.com