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CLINDATRIX JOINS SIX OTHER CROS TO PROVIDE GLOBAL SERVICES

Collaboration Will Ensure Local Monitoring and Centralized Clinical Research Technology for Sponsors of Multinational Clinical Trials

IRVINE, CA, May 15, 2014 – ClinDatrix, Inc. has signed collaboration agreements with six contract research organizations (CROs) from around the world to form a consortium that offers services for multinational clinical trials. On joint projects, consortium members will provide clinical trial project management, clinical monitoring, site management and regulatory submission guidance in their respective regions and rely on ClinDatrix for its clinical research technology.

"ClinDatrix has always drawn on trusted CROs for clinical monitoring support of trials outside of the United States and Canada," said Louise M. Murphy, PhD, MBA, President and CEO of ClinDatrix. "This collaboration solidifies that practice. It also reflects our belief that strong, small, regional CROs can deliver more personalized, high quality services to pharmaceutical, biotechnology and medical device developers at a value price as compared to large CROs."

Each of the global collaborators provides clinical research expertise in the languages and customs of their countries and in compliance with their governing regulatory agencies. Their in-depth understanding of the local culture, processes and language(s) will help all of the members of the consortium better serve study sponsors, investigator site staffs, and the study participants.

"In addition, membership in the consortium gives our partners access to the depth of clinical research technology that ClinDatrix brings to the table," said Brian G. Murphy, PhD, ClinDatrix Chairman and CFO. ClinDatrix will support the collaborative projects with its expertise in electronic data capture (EDC), LORENZ DocuBridge electronic common technical document (eCTD), SharePoint/Montrium and Oracle Argus safety systems. "ClinDatrix hosts its own Oracle database systems and can support other sponsor-selected systems as well," he said.

The consortium members are:

- ClinDatrix – covers the United States and Canada from its headquarters in Irvine, California
- ClinActis Pte. Ltd. – serves Asia Pacific clients from its headquarters in Singapore and operations in Hong Kong, Philippines, Malaysia, Thailand, South Korea, Taiwan and Australia

- DOKUMEDS SIA – supports trials in Central Eastern Europe from its operations in Latvia, Lithuania, Estonia, Ukraine, Russia, Poland and Romania
- DOT International – based in Tokyo and covers Japan
- OnQ Research PTY LTD – serves African clinical sites from its headquarters in South Africa
- Research & Development RA S.A. – covers Central and South America from its headquarters in Argentina
- Venn Life Sciences – serves European clinical sites from its headquarters in Ireland and offices in England, France, Germany and the Netherlands

"This global collaboration positions all of us to better compete for large, multinational projects," said Christophe Tournerie, MD, Founder and CEO of ClinActis. "The companies' strengths and locations are complementary, so together we offer sponsors the services of a large CRO with the proximity to market, personal attention and responsiveness that each of the collaborating firms provide their clients." He added, "ClinActis brings to the consortium unique and dynamic expertise in applying global drug development standards to the specificities of each country in the Asia Pacific region."

"Clinical trials increasingly are conducted across multiple countries," said Tony Richardson, CEO of Venn Life Sciences. "We believe our consortium of similar CROs will enable all of the participating companies to better support our clients' needs and to secure larger and later stage studies."

One strength of the collaboration mentioned by Tetsuya Orito, DOT International Chief Operating Officer and President, is the consortium's ability to provide an effective development strategy to sponsors targeting the Japanese market. "Japan has the world's second largest market with growing needs for healthcare solutions," he said. "Because of their unfamiliarity with the regulatory policies of Japan, many American and European pharmaceutical manufacturers are still hesitant to promote their products here. Working with our consortium may increase sponsors' confidence in involving Japan in their global development plans."

Catherine Lund, Managing Director of OnQ noted that the collaboration of smaller CROs "adds incredible value for the smaller drug and device developers. Using our full consortium, or one or two of our firms, will give early stage sponsors the geographic scale they need at a cost-effective fee."

Indra Āboltiņa, MD, PhD, Chief Executive Officer and Member of the Board of DOKUMEDS concurred. "Working together through this agreement, we can draw on one another's strengths." She said that DOKUMEDS brings access to key opinion leaders and clinical sites in Central Eastern Europe, a region of growing interest to large pharmaceutical and biotechnology companies. "As the Central Eastern European arm for our consortium, we hope to secure more work for our team while enhancing the capacity of our partners' firms, too."

In terms of securing new projects, Pablo Liuboschitz, CEO and Executive Director of Research & Development, said, "We have seen that the collaboration has already enabled us to respond more quickly to sponsors' requests for proposals. Instead of winning work on our own and then seeking clinical research resources in the applicable countries, we can present our team in the proposal stage. We believe that strengthens our bids and adds transparency to our proposals."

About ClinDatrix, Inc.
ClinDatrix (www.clindatrix.com) is a contract research organization (CRO) that serves the pharmaceutical, biotechnology and medical device industry globally. Founded in 2002, the company offers comprehensive project management, clinical monitoring, medical safety, data management, biostatistics, medical writing, regulatory affairs, and quality assurance services, primarily to small and mid-sized pharmaceutical, biotechnology and medical device innovators.

About ClinActis Pte. Ltd.
ClinActis Pte. Ltd. (www.clinactis.com) is a full service CRO providing clinical trial services to the pharmaceutical, medical device, medical nutrition and biotech companies in Asia Pacific. Established in 2009, ClinActis is headquartered in Singapore. Our goal is to become the reference CRO specialized in conducting clinical research in Asia Pacific, offering state of the art quality services, with cost effective solutions. Our services include consultancy on product development strategy in Asia Pacific, clinical project management, site management, clinical monitoring, clinical research and ICH GCP training, and temporary clinical staffing.

About DOKUMEDS, SIA
DOKUMEDS (www.dokumeds.com) is a business solutions and quality driven European CRO that provides services for clinical research and development to the pharmaceutical, biotechnology and medical device industry worldwide. Established in 1995, DOKUMEDS employs nearly 100 people in different countries who support trials in many of the European Union (EU) and non-EU countries of Central Eastern Europe. Via its ISO 9001:2008 and GDP certified depot in Moscow, DOKUMEDS provides IMP and clinical supplies storage and distribution services in Russia. DOKUMEDS holds ISO 9001:2009 certification and is involved in the development of the world's most modern and powerful medicinal products.

About DOT International
DOT International (www.crodot.jp) was founded in 2006 in Tokyo, Japan as a full-service CRO. DOT provides business support for pharmaceutical companies in clinical trials including post-market and investigator-initiated trials. Within the past eight years, DOT has successfully supported four NDAs and contributed to the marketing of numerous drugs and medical devices. DOT provides a one-stop service including negotiation with Japanese regulatory authority, consultation for clinical development plans in Japan and support for clinical trial management in China. Our mission is to shorten the timeline for the clinical development of medicines and medical devices for their manufacturers as well as patients in need. Through the global consortium, DOT believes it can help sponsors utilize their global data toward product approval in Japan.

About OnQ Research PTY LTD
OnQ Research PTY LTD (www.onqsa.co.za) was founded in 1999 in Johannesburg, South Africa, as a niche provider of expert clinical research services. The firm facilitates full clinical trials in South Africa and supports studies at sites throughout Africa. OnQ is uniquely placed to provide monitoring and project management services to pharmaceutical, biotechnology and medical device companies and to CROs. OnQ has been involved in over 120 clinical trials, with an extensive client database that includes major pharmaceutical companies, biotech companies, medical device companies, international CROs, donor/government-funded research and academic institutions.

About Research & Development RA S.A.
Research & Development RA S.A. (www.rd-latam.com) is a Buenos Aires, Argentina-based CRO that was created to provide clinical research services to the pharmaceutical and biotechnology industries covering the most important pharmaceutical markets in Latin America. Through our extensive experience, uncompromising quality, global presence and cost effective services, we are committed to the success of our clients' clinical programs.

About Venn Life Sciences Limited
Venn Life Sciences (www.vennlifesciences.com) is a CRO providing a suite of clinical trial management services to pharmaceutical, biotechnology and medical device organizations. Celebrating 25 years in business in 2014, Venn has operations in France, Germany, Ireland, the Netherlands, Russia, Switzerland, the UK and an extensive network of partners throughout Europe. The company has recently been expanding its European operations whilst enhancing its portfolio of its innovative technologies division, InnoVenn, with ground breaking new products and services.

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