



Rondaxe and TD2 form strategic drug development alliance

TGen Drug Development (TD2) gets skills in drug manufacturing and quality control, Rondaxe receives access to TD2's expertise in clinical trials and regulatory navigation

SAN FRANCISCO — Feb. 18, 2010 — TGen Drug Development (TD2) and Rondaxe Enterprises today announced a strategic alliance that will help emerging companies speed new high-quality treatments to cancer patients.

Rondaxe, a drug development consulting company in Syracuse, N.Y., helps emerging pharmaceutical and biotechnology companies navigate through all phases of the drug development and commercialization process. The company specializes in drug chemistry, manufacturing and controls (CMC), quality assurance and control, regulatory affairs and virtual business development.

TD2, a non-profit Scottsdale subsidiary of the Phoenix-based Translational Genomic Research Institute (TGen), specializes in guiding drug companies through the complexities of setting up and conducting clinical trials, and moving promising drug candidates through the federal review process of the U.S. Food and Drug Administration.

“We are excited to work with Rondaxe, since effective CMC management is key to the successful application and approval processes of the FDA, and moving new anti-cancer treatments to market where they can provide patient benefit,” said Dr. Stephen Gately, President and Chief Science Officer at TD2.

Jeffrey M. Evans, Ph.D., co-founder and managing partner of Rondaxe, said, “Our clients will benefit measurably from the ‘TD2 Solution’ by receiving clear clinical and regulatory development path guidance and service support.”

Today’s announcement was made during InformexUSA, the world’s leading fine and custom chemical industry trade show, which runs through Friday, Feb. 19, at the Moscone Convention Center in downtown San Francisco.

The TD2-Rondaxe alliance is designed to bridge a critical gap between chemistry and translational medicine. This blend of expertise will speed research discoveries through the regulatory process to bring new compounds to patients in a risk-reduced and cost-effective manner. TD2 and Rondaxe teams will focus on maximizing their clients' value proposition throughout the early stages of drug-development.

Rondaxe will provide drug development and manufacturing strategies with expertise in chemical, fermentation, drug product and analytical development, supply chain strategy, manufacturing operations, quality control, and quality assurance.

TD2 offers an integrated suite of tools that includes preclinical support, clinical trials and regulatory affairs, "The TD2 Solution."

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About Rondaxe Enterprises

Rondaxe Enterprises is a unique company providing a suite of services that combines expert drug development consulting, in-depth project management leadership, software applications and virtual business development designed specifically for emerging pharmaceutical and biotech companies. Rondaxe is led by four managing members, a team of experienced industry executives and more than 50 senior advisors, most of whom have 15-30 plus years of industry experience, with a vision and an unflinching dedication to clients' success. Founded in 2003, Rondaxe has enjoyed steady growth based on a proven track record in delivering results, establishing solid relationships with customers, and a strong commitment to expand skills and product offerings as customer's needs expand.

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About TGen Drug Development (TD2)

TD2, a wholly owned subsidiary of the Translational Genomics Research Institute (TGen), is a 501(c)3 non-profit organization. TD2 provides innovative services for oncology-focused biopharmaceutical companies using a dedicated team of professionals with broad experience and understanding in drug development. TD2 is uniquely positioned to support the need for improved and accelerated development of new chemical entities (NCE's) for life-threatening diseases. TD2 uses a unique combination of experience gained through its contract research organization business, and an integrated suite of proprietary and non-proprietary tools, preclinical study execution, regulatory affairs assistance, clinical trial design and management, and drug development experts to successfully move therapeutics towards regulatory approval. TD2 is dedicated to reducing the risks and uncertainty inherent in the drug development process. For more information, please visit: www.td2.org.

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About TGen

The Translational Genomics Research Institute (TGen) is a Phoenix, Arizona-based non-profit organization dedicated to conducting groundbreaking research with life changing results.

Research at TGen is focused on helping patients with diseases such as cancer, neurological disorders and diabetes. TGen is on the cutting edge of translational research where investigators are able to unravel the genetic components of common and complex diseases. Working with collaborators in the scientific and medical communities, TGen believes it can make a substantial contribution to the efficiency and effectiveness of the translational process. TGen is affiliated with the Van Andel Research Institute in Grand Rapids, Michigan. For more information, please visit: www.tgen.org.

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