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PRESS RELEASE

Former FDA lawyer Laurie Clarke joins TSG Consulting to lead medical device practice

WASHINGTON DC – 10 March, 2021: Laurie Clarke, JD, MPP joins TSG Consulting as Vice President & Principal of the company's medical device regulatory practice. With over 25 years of experience as a Food and Drug Administration (FDA) lawyer, Laurie is a known leader in medical device regulation, from premarket submissions to FDA enforcement actions. In this newly created position, Laurie will lead TSG Consulting's established medical device regulatory team, as well as collaborate with medical device advisory and product development colleagues at sister company Sagentia, to help clients deliver FDA-compliant, innovative medical devices across the patient care continuum. TSG Consulting and Sagentia are both Science Group companies.

Erin Tesch, MD of TSG Consulting in North America, says: "Laurie's vast experience allows Science Group to play a greater role in supporting clients through both product development and the required FDA approvals in the US. TSG is the only company that we are aware of that offers both medical device development and in-house FDA and EPA regulatory expertise."

Rob Morgan, PhD, Managing Partner Medical, Sagentia adds: "We work with many companies planning innovation strategies as well as designing and developing breakthrough medical products. With Laurie's deep understanding of the FDA regulatory processes, clients now have a partner that can provide more support in new product regulation from concept to launch, so expanding the service we offer."

Laurie Clarke notes: "Science Group's thriving and dynamic medical device product development and regulatory practices attracted me to the company. At TSG, I have the rare opportunity to help clients shape their FDA regulatory strategy, including the design of their clinical studies, while their medical devices are in the early stages of development. I am excited because at that stage the client has maximum flexibility to align the device's technology, marketing claims, and regulatory path. In addition, the client benefits from working with an integrated team. This approach promises to be cost effective as it reduces the FDA regulatory risks and thus makes it more likely our clients will obtain FDA clearance or approval to market their devices sooner."

TSG Consulting ¬
1150 18th Street, NW
Suite 1000, Washington, DC 20036
T +1 (202) 828-8990
E info@tsgconsulting.com
www.tsgconsulting.com

Laurie received her law degree from Stanford University after obtaining a Masters in Public Policy (MPP) with a concentration in health policy from Harvard University and an AB *cum laude* from Smith College. She started her career as an FDA lawyer at Patton, Boggs and Blow. While at that firm Laurie obtained public acknowledgement that her client wrote the original Nancy Drew books under the pen name "Carolyn Keene." As an FDA partner, Laurie helped expand the medical device practices at three top-ranked law firms – Hogan & Hartson, King & Spalding LLP, and Jones Day. Most recently Laurie was Executive Vice President, Medical Devices & Combination Products at Greenleaf Health Inc., a boutique FDA consulting company. Throughout her career, Laurie has represented medical device companies ranging from small start-ups to multi-national corporations on complex regulatory matters involving a wide variety of medical devices.

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Contact

Lucy Beverley

Marketing Manager – TSG Consulting

E: lucy.beverley@sciencegroup.com

About TSG Consulting

TSG provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting is a Science Group company.

www.tsgconsulting.com

About Sagentia

Sagentia is a global science, product and technology development company. Our mission is to help companies maximise the value of their investments in R&D. We partner with clients in the medical, consumer, industrial and food & beverage sectors to help them understand the technology and market

landscape, decide their future strategy, solve the complex science and technology challenges and deliver commercially successful products. Sagentia employs over 150 scientists, engineers and market experts and is a Science Group company.

www.sagentia.com

About Science Group

Science Group plc (AIM:SAG) is a science-led advisory and product development organization. The Group has three divisions:

- R&D Consultancy: providing advisory, applied science and product development services cross-sector helping clients derive maximum return on their R&D investments.
- Regulatory & Compliance: helping clients in highly regulated markets to launch, market and defend products internationally, navigating the frequently complex and fragmented regulatory ecosystems.
- Frontier Smart Technologies: designing and manufacturing chips and modules for the DAB/DAB+ radio markets with 80% market share (excluding the automotive market).

With more than 400 employees worldwide, primarily scientists and engineers, and speaking more than 30 languages collectively, the Group has R&D centres in Cambridge and Epsom with more than ten additional offices in Europe, Asia and North America.

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