FOR IMMEDIATE RELEASE

CONTACT INFORMATION
Julia Rudeau
DSG Inc.
+1 (484) 913-2175
jrudeau@dsg-us.com

DRUG APPROVED IN PIVOTAL STUDIES USING DSG'S FULLY ELECTRONIC SOURCE DATA

MALVERN, PA., March 3, 2015 – DSG, Inc and Sirion Therapeutics collaborated in launching the industry's first two pivotal Phase 3 studies using entirely electronic source data collection for the safety and efficacy of Difluprednate in the management of inflammation following ocular surgery.

Thanks to the novel and innovative methods used during the study, Sirion received FDA approval of Difluprednate.

100% eSource and the fully integrated eCaselink system enabled remote monitoring by Sirion's in-house CRAs. There were fewer anomalous data points and the data was cleaner upon data entry due to the proprietary nature of the eCaseLink edc system, making use of a far higher quantity of complex edit check protocol validations than what would be considered industry standard. Company executives were kept current on the progress of the study via reports generated within the eCaselink system. Due to the efficiencies of eSource, the time to database lock following last subject - last visit was significantly shorter, allowing Sirion to proceed to conducting the analysis and to receive study results expeditiously.

"Electronic source made the most practical and economic sense; however in researching the topic, we discovered a lack of FDA guidance, an absence of industry case studies, and no subject matter expertise such as consultants with experience in submitting a 100% electronic source study to the Agency," said Kim McLeod, Vice President of Clinical Operations (currently Director, Prospective Research at Xcenda).

When the FDA conducted in-house and site audits as part of the NDA process, Sirion and DSG worked together to support the use of eSource captured via eCaselink edc with IWRS (randomization with drug tracking and allocation). The FDA auditor assigned to Sirion was unaccustomed to these methods of data collection and drug tracking, however, could easily understand the validations and documentation. The auditor thoroughly investigated the database design and validation; data collection process at the sites; drug accountability and tracking; and remote monitoring procedures - and closed the audit with a positive review, ultimately leading to FDA approval.

"The objective was to enroll 120 subjects into each study quickly, and from start to finish – complete the development, preparation, execution, enrollment, analyses and reporting of the studies in less than six months and within a tight budget. Centers were ophthalmic surgical

suites with varying degrees of clinical trial experience. The need for a mobile data collection process was imperative to the success of the study as data collection would come from originating sources to include the surgical investigators, study coordinators and EMRs. We needed an intuitive, all encompassing, reasonably priced data collection system in order to obtain reliable data in real time while managing study related costs. A mobile data collection process was critical due to the various sources and the need for investigators to remain in motion. DSG responded by designing, programming, validating and launching a single seamless solution. Sirion provided each site with a wireless tablet and equipment required for wireless access to the EDC system that allowed them to enter patient data directly into the EDC system. Electronic source and the use of WIFI internet-enabled tablets gave surgeons and study coordinators the mobility they coveted while completely eliminating paper source documentation which removed the need for source data verification, and thus dramatically decreased monitoring time and costs for Sirion," said Kim.

"As one of the original EDC companies taking a product to market back in 1999, we remember well the push-back against what was then a new technology promising to substantially reduce resources needed to conduct a trial. eSource for pivotal studies was also regarded as taboo amidst warnings and fear mongering of NDA rejections when in fact, FDA desires eSource, and so here is your proof, " said Tony Varano, CEO of DSG. "We are always excited to see new applications complimenting EDC and dramatically reducing resources required to perform a clinical trial. Eliminating paper data review with eSource and now with risk-based monitoring are resource game changers for our industry."

About DSG

DSG, Inc. supports clinical data capture and management with a proprietary, organically integrated suite of award-winning user-friendly technology solutions, including flagship eCaseLink™ EDC, ePRO, IWRS, Drug Safety, and CTMS. Since 1992, DSG has successfully supported thousands of clinical trials for over 400 companies and 25,000 sites across 93 countries, headquartered in Malvern, Pa., with additional offices in the U.S. and Asia: www.dsg-us.com.

###