Medidata Synthetic Control Arm® Supported by the US Food and Drug Administration (FDA) for Use in Medicenna Therapeutics, Corp. Phase 3 Registrational Trial in Recurrent Glioblastoma

Marks precedent setting acceptance of synthetic control arm for a phase 3 trial

NEW YORK (October 28, 2020) – Medidata, a Dassault Systèmes Company, today announced that the US Food and Drug Administration (FDA) supported the use of a Medidata Synthetic Control Arm® in a phase 3 registrational trial in recurrent glioblastoma (rGBM). This is a precedent setting acceptance of a hybrid external control (combining synthetic control arm patients with randomized patients) in a phase 3 trial in an indication that previously used traditional randomized controls.

Medicenna Therapeutics, Corp. (NASDAQ: MDNA, TSX: MDNA), a clinical stage immunotherapy company, will use a hybrid external control arm in a phase 3 registrational trial in recurrent glioblastoma, an aggressive form of brain cancer. The hybrid external control arm will reduce the number of patients required to be assigned to the control therapy in the trial, will provide rigorous scientific data, and will enable speedier development of the product. The phase 2 single arm trial preceding this phase 3 study was also enhanced by a synthetic control arm and estimates of the treatment effects based on the synthetic control arm were part of the briefing information provided to the FDA for justification of the use in phase 3.

“We are pleased with FDA’s acceptance and look forward to creating a highly rigorous scientific comparison to support development of Medicenna’s MDNA55 for recurrent glioblastoma,” said Ruthie Davi, vice president, Data Science, Acorn AI by Medidata. “There are no established therapies to prolong life for people suffering with rGBM, so the hybrid external control arm could provide great hope for patients with this disease.”

“We are extremely impressed with the Acorn AI team for providing a scientifically rigorous rationale for the design of an innovative registration trial incorporating an external control arm for the treatment of recurrent glioblastoma (rGBM) with MDNA55. Their expertise and collaborative effort with thought leaders was instrumental in demonstrating to the FDA the validity of a well designed external control in a registration trial,” said Fahar Merchant, PhD, president and CEO, Medicenna Therapeutics, Corp. “The FDA’s acceptance of this unique

design will expedite completion of the Phase 3 trial in rGBM, allowing earlier access of MDNA55 for a disease with poor prognosis and high unmet need."

Synthetic control arms are formed by carefully selecting patients from historical clinical trials to match the demographic and disease characteristics of the patients treated with the new investigational product. They have great potential to enhance single arm trials and enable more efficient randomized clinical trials in indications where the standard of care therapy is impracticable or unacceptable to patients.

Medidata is a wholly owned subsidiary of Dassault Systèmes, which with its 3DEXPERIENCE platform is positioned to lead the digital transformation of life sciences in the age of personalized medicine with the first end-to-end scientific and business platform, from research to commercialization.

About Medidata
Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostic companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,600+ customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at www.medidata.com and follow us @Medidata , The Operating System for Life Sciences™.

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Dassault Systèmes, the 3DEXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative 3D virtual environments to imagine sustainable innovations. By creating virtual experience twins of the real world with our 3DEXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production. Dassault Systèmes brings value to more than 270,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit www.3ds.com.

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