Clinical Trial Standards Policy

Axsome is deeply committed to ensuring that our clinical trials are well-designed and conducted responsibly and transparently, in full compliance with applicable laws and regulations, with adherence to the highest ethical and quality standards. We value protecting patient data and the rights and well-being of the participants in our clinical trials. We are proud to have dedicated and trained staff to ensure timely registration of clinical trials and communication of our research results, and we work closely with external experts and thought leaders to ensure our work reflects the latest clinical and scientific advances.

This policy applies to all Axsome sponsored clinical trials, including clinical trials administered by contract research organizations or academic research organizations on Axsome's behalf, and clinical trials undertaken through joint ventures and other partnership arrangements.

Our current practices include:

- Consent – Our approach includes promoting transparency in our informed consent process. All participants (or legally acceptable representative) must provide their written consent to participate through a thorough and documented informed consent process before any study related procedures are performed. The process ensures that participants understand the study purpose, potential benefits and risks and alternative treatment options.

- Data Privacy – As guardians of data about the patients who use our medicines, as well as their caregivers and the healthcare professionals who serve them, we are committed to handling personal data in accordance with global laws and regulations that govern data protection and privacy.

- Clinical Trial Registration – We register company-sponsored clinical trials on public clinical registry sites as required by global laws and regulations.

- Clinical Trial Results – The Company acknowledges the benefits of timely disclosure of clinical-trial findings for both patients and the scientific community. We disclose company-sponsored clinical trial results on public registries in accordance with global results disclosure laws and regulations.

- Publicly Accessible – Information regarding the protocol, status and results of clinical trials is available on publicly accessible registries and platforms, as well as through presentations at international conferences and publications in scientific journals.

- Protocol – All of our clinical trials are designed and conducted in line with the International Conference on Harmonisation of technical requirements for

registration of pharmaceuticals for human use and Good Clinical Practice (ICH GCP), the Declaration of Helsinki, and in accordance with international, national and local regulations, keeping participant safety and quality standards front and center. All of our trials are designed to meet the strict requirements of the U.S. Food and Drug Administration (FDA), and comparable regulatory agencies in state and local jurisdictions and in foreign countries, as applicable. Furthermore, we ensure our trial protocols are reviewed and approved by a qualified Institutional Review Board or Ethics Committee prior to trial initiation. We take responsibility for ensuring that each of our clinical trials is conducted in accordance with an investigational plan and protocol that is in conformity with all regulatory requirements and approvals.

- Patient Safety – All clinical trial participants are continuously monitored by the study doctor throughout the course of the study to protect their health, prevent harm and ensure that the products maintain a positive benefit-risk profile, with timely discussions of findings with participating investigators.

- Contract Research Organizations ("CROs") – At Axsome, we work with CROs and other vendors to support clinical trial efforts, and all such are required to undergo a vendor qualification procedures. We expect our CROs and vendors to adhere to these guidelines and we accomplish this by conducting regular monitoring and quality checks of our outsourced obligations. The Company works closely with all partners with the goal of ensuring that study conduct is consistent with the clinical trial protocol and that the rights, safety, and well-being of the trial participants are protected, consistent with ethical standards and regulatory requirements.