Gedeon Richter's Position
on the Conduct of Clinical Trials and Trial Data Transparency

At Gedeon Richter our mission is to provide high-quality medicines worldwide at affordable prices. This mission requires thoughtful strategies and policies during all phases of our R&D programs, including clinical trials, which are grounded in the core values and highest ethical standards of the company.

Clinical trials – research studies involving human participants – are critical and essential steps in bringing new medicines to patients and to evaluate the efficacy and safety of these drugs. These studies also provide important information needed to obtain approval from governmental health authorities in order to bring new products to a diverse population of people in dire need. Therefore, our commitment is to conduct clinical research in a way that promotes mutual trust between patients, physicians, Gedeon Richter as the pharma company, local ethics committees and governmental authorities. To promote this collaboration our approach includes:

Adhering to both internal and external regulations:

To provide the utmost safety and wellbeing of trial subjects, we have established a set of strict policies and standard operational procedures which clearly define the processes of clinical trials. The fundamentals of these scientific and ethical standards are derived from the most highly respected international codes such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 guideline for Good Clinical Practice and the Declaration of Helsinki. All employees working in clinical trials are regularly trained on both these standards and internal processes.

All Gedeon Richter-sponsored clinical trials are conducted in accordance with local laws and regulations and the above-mentioned policies are strictly followed even when the studies are conducted collaboratively with another sponsor, contract research organization or any third party. Regular and risk-based qualifications and audits are performed both at vendors and clinical sites to ensure that Richter's standards are met even when clinical trials are outsourced.

Gedeon Richter will always seek approval for its clinical trials from independent ethics committees and/or institutional review boards before initiating any trial-related activities at a clinical site to protect the rights and wellbeing of study participants. Based on emerging data, these independent ethics committees also have the authority to modify or stop ongoing trials. Managerial responsibility for ethical conduct in clinical trials lies with Richter's Director of Research and Development.

Providing scientific integrity in our trials:

The risk-benefit evaluation of a clinical study heavily depends on the pre-clinical R&D results and processes. At Gedeon Richter we believe that extensive, reliable, and reproducible pre-

clinical data is essential to develop a clinical trial protocol to answer successfully and safely the unmet needs of patient populations.

We select sites to implement clinical trials based on the capabilities of the sites and we strongly consider during site selection if there is a medical need for our potential therapy in the specific countries in question. We only conduct clinical trials involving patients in countries where we intend to market the investigational product directly or through partners. We are committed to select the appropriate patient population for our clinical trials solely on scientific grounds in order to enrol and gain data from as diverse population as possible, representative for the disease and the region.

Since data integrity is also a key factor in drug development, we have internal guidelines and oversight mechanisms in place to ensure the accuracy and security of the data that our trials generate.

Gedeon Richter's quality management and pharmacovigilance system provides continuous quality assurance and safety not only during the clinical development but throughout the entire lifespan of a compound.

Providing safety and care for patients during and post-trial:

At Gedeon Richter we recognise that both patients – those who have some health issues – and healthy volunteers play a vital role in clinical trials and we are committed to respect their rights, protect their health, and provide consistent standard of care throughout the study.

We have procedures in place to ensure that study participants can make a free and informed prior decision about whether to participate in a study. They are given relevant information about the treatment option they are considering as well as information about available alternative therapeutic options. Trial subjects are fully informed of the potential benefits and risks of the study, and we prioritise educating them on the voluntary nature of every study. Participants are allowed to withdraw their consent at any time during the study without penalty or loss of benefits to which the subject is otherwise entitled.

Information provided to clinical trial participants is reviewed first by external institutional review boards and independent ethics committees. Also, we are committed to protect the confidentiality of their private information, and to provide extra attention and protection for vulnerable populations.

We follow the guidelines of ICH-GCP and ensure patient safety with meticulous CRO oversight even if study monitoring is outsourced. As part of the informed consent process, participants are informed regarding the appropriate channels to express their questions, concerns or complaints.

We offer continuity of treatment – in collaboration with local authorities – for patients who completed a Gedeon Richter sponsored clinical trial and are still deriving benefit from our treatment.

Committing to openness and transparency behind our products:

At Gedeon Richter, we believe that clinical trial data transparency advances medicine and is in the best interest of the patients who use our products. Hoping to build trust between all participants of the clinical trial processes, we are committed to open communication and the truthful, complete and accurate reporting of trial data.

We are committed to meet regulatory requirements for the registration of our clinical trials, and our policies are designed to promote effective and ethical reporting of trial results at the end of every study. All Gedeon Richter sponsored studies conducted in patients are registered and reported in publicly accessible registries, such as EudraCT or ClinicalTrials.gov, according to the local laws and regulations where the clinical study is conducted.

Before study initiation (first patient first visit), all Phase I-IV studies involving patients are registered in one of the publicly accessible databases such as EudraCT or ClinicalTrials.gov and published according to the local laws and regulations. After study completion (including early termination) and regardless of outcome, our Phase II-IV study results are shared in publicly accessible registries such as EudraCT and ClinicalTrials.gov according to the regional regulations where the study was conducted. In addition, if study participants wish, we are open to share clinical trial results in easy-to-read format using non-technical language so that they can understand more about the research they have contributed to.

Gedeon Richter ensures that for scientific publications only those authors are listed who contributed to the design, data generation, analysis, interpretation, drafting/reviewing and final approval of the given publication. All authors adhere to the guidelines of the publisher regarding disclosure of support and conflicts of interest.