EXTERNAL LUNDBECK POSITION PAPER 2014

RESPONSIBLE CLINICAL TRIAL DATA SHARING

Background

In accordance with EFPIA's and PhRMA´s "Principles for Responsible Clinical Trial Date Sharing" guidelines, Lundbeck is committed to responsible sharing of clinical trial data in a manner that is consistent with: safeguarding the privacy of patients, respecting the integrity of national regulatory systems and protecting the intellectual property of the sponsor. The protection of intellectual property ensures continued research and innovation in the pharmaceutical industry. Lundbeck aims to have the procedures and policies in place in order to comply with this commitment during the first half of 2015. Lundbeck's mission is to improve the quality of life of people suffering from psychiatric and neurological disorders. As a pharmaceutical company, Lundbeck considers the sharing of information from company-sponsored clinical trials to be an important part of fulfilling this mission. The sharing of clinical trial information will enable the medical and scientific community in the further understanding of the diseases and their treatment for the future benefit of patients.

Information available for researchers

Following approval of a new product or a new indication for an approved product in both the European Union (EU) and the United States (US) and where the application has been approved after 1 January, 2014, Lundbeck will share study protocols, anonymized patient data and redacted clinical trial reports from clinical trials with qualified scientific and medical researchers, as necessary for conducting legitimate research.

Data and information sharing with researchers

Lundbeck will provide access to anonymized, patient-level data and other relevant information from clinical trials for pharmaceutical products within the indications approved in US and EU. The access will be consistent with the principle of safeguarding patient privacy and in accordance with the patients' informed consent provided in relation to their participation in the clinical trial. To obtain access, independent qualified scientific and medical researchers must submit a request containing the following: A Research Proposal including hypothesis and rationale, a Statistical Analysis Plan (SAP) and a signed "Access to Data and Information Data Sharing Agreement". Templates for application forms will be available at www.Lundbeck.com during the first half of 2015. Access to data will be provided following a thorough review of the request by a scientific review board including external independent academic scientists/healthcare professionals. The above described procedure will be in place only as long as no other mandatory procedures have been implemented by health authorities, e.g. the EMA POLICY/0070 regarding publication and access to clinical-trial data.

Results summaries for clinical trial participants

Information to clinical trial participants is of importance for Lundbeck. Lundbeck and its industry peers are working with regulators to adopt mechanisms through which companies can share clinical trial information with subjects who participated in a particular clinical trial, consistent with local legislation. At the moment, this information is available through the individual clinical trial investigators.

Protocols and results reporting

Lundbeck registers clinical trial protocol information and discloses results of clinical trials, regardless of outcome, in a publicly accessible clinical trial registry, www.clinicaltrials.gov. In addition, clinical trial protocol and result information submitted by Lundbeck to the EudraCT database is made publicly available by the EMA via its clinical trial registry, www.clinicaltrialsregister.eu. Clinical trial reports will be accessible on the EudraCT site in accordance with the EMA POLICY/0070.

Publications

Lundbeck encourages publication of the results from research and discovery and from clinical studies of its products and drug development candidates, irrespective of whether the results are positive or negative, and acknowledges a special obligation to publish data related to patient safety. At a minimum, Lundbeck will submit for publication the results of all Lundbeck-sponsored phase III clinical studies and the results of any other clinical studies of significant medical importance, primarily in peer-reviewed journals or as abstracts, posters, or other presentations at scientific meetings. Publication activities will be undertaken responsibly and ethically to ensure that all relevant information is communicated clearly and in a timely manner.

Wherever possible, primary phase III manuscripts will be submitted no later than 18 months after clinical trial completion for approved products. This also applies to drug development compounds for which development has been discontinued.