Expanded Access Policy – Glyburide Oral Suspension (Investigational)

Eton Pharmaceuticals is developing glyburide oral suspension for the treatment of neonatal diabetes mellitus and is committed to advancing the program as efficiently as possible through clinical development and regulatory review.

Currently, Eton's primary focus is completion of the ongoing clinical development activities necessary to support submission of a New Drug Application. Accordingly, Eton is not currently providing investigational glyburide oral suspension through an expanded access (compassionate use) program.

Following completion of the planned near-term clinical development activities, including the bioavailability study supporting the planned NDA submission, Eton may evaluate whether an expanded access program is feasible prior to FDA approval. Any decision to provide expanded access will depend on several factors, including but not limited to:

- The seriousness of the patient's condition and unmet medical need;
- The availability of alternative treatment options;
- Whether the potential benefits are judged to outweigh the potential risks;
- Adequate supply of investigational product; and
- Whether providing expanded access would not interfere with the clinical development program or regulatory review.

Eton reviews expanded access requests on a case-by-case basis. Publication of this policy does not guarantee that investigational product will be made available to any individual patient.

If Eton determines that expanded access is appropriate for any particular patient, treatment will remain subject to applicable FDA regulations and Institutional Review Board (IRB) requirements.

Treating physicians with questions regarding expanded access may contact Eton Pharmaceuticals at etonmc@eversana.com or 1-855-224-0233.