Product Name	COR-003
Active substance	2S, 4R ketoconazole; levoketoconazole
Indication and conditions of use	COR-003 is being developed for the treatment of Cushing´s syndrome (CS).
Conditions, delays and further rules for participation of patients	***Inclusion Criteria*** Patients will be eligible for participation in the program only if they meet ALL of the inclusion criteria. 1. Patient has completed the Extended Evaluation Phase in Study COR-2012-01, and, in the opinion of the Physician, continued treatment with COR-003 may be beneficial to the patient. Note: Patients who are currently in Named Patient Programs (or equivalent) that meet this criterion are also eligible. 2. Able to provide written informed consent prior to any program procedures being performed; eligible patients must be able to understand the informed consent form prior to inclusion into the program. 3. A female is eligible to enter and participate in the program if she is: • Of non-child bearing potential (i.e. physiologically incapable of becoming pregnant, including any female who is post-menopausal or surgically sterile). Surgically sterile females are defined as those with a documented hysterectomy and/or bilateral oophorectomy or tubal ligation. • Post-menopausal females are defined as being amenorrheic for >1 year with an appropriate clinical profile (e.g. >45 years of age) in the absence of hormone replacement therapy. **OR** • Of child bearing potential and agrees to use highly effective methods of birth control, as defined in Section 6.2.5 of this protocol, while participating in the program and for 2 weeks after the last dose of COR-003. 4. Fertile men must also agree to use a medically acceptable form of birth control, as defined in Section 6.2.5 of this protocol, while on COR-003 and for up to 2 weeks after their last dose of COR-003. 5. Able to comprehend and comply with procedures. ***Exclusion Criteria*** Patients will not be eligible for participation in the program if they meet ANY of the exclusion criteria. 1. Patients who were discontinued/withdrawn from COR-2012-01 or permanently discontinued COR-003 while participating in COR-2012-01 or in a named patient or equivalent program due to safety, tolerability or efficacy concerns. 2. Female patients who intend to conceive during the course of the program. 3. Any medical condition or circumstances that, in the opinion of the Physician, might interfere with the patient's participation in the program or pose any added risk for the patient. 4. Patients scheduled for surgery or radiation therapy for treatment of CS after

	completing the parent study (COR-2012-01). 5. Patients who have developed clinical or radiological signs of compression of the optic chiasm since starting COR-003. 6. Patients with clinically significant abnormality in 12-lead ECGs (Appendix 4 of this protocol) during the EAP screening assessment 7. LFTs must not be above the following cut-offs during the EAP screening or baseline visits: • Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) >3 times upper limit of normal (ULN). • Total bilirubin (TBN) >2 times ULN. 8. Patients who have developed decreased renal function as defined by an estimated glomerular filtration rate (eGFR) <40 mL/min/1.73 m_2, using the Modification of Diet in Renal Disease (MDRD) equation for estimating renal function since enrolling in COR-2012-01. 9. Patients who have abused alcohol or drugs since enrolling in COR-2012-01. 10. Patients who plan to receive or need any prohibited concomitant medication, including: • Acetaminophen >3 g total daily dose (due to increased hepatotoxicity); • Co-administration of strong inducers or inhibitors of CYP3A4 enzyme system or P-glycoprotein (P-gp) inhibitors that may interfere with the metabolism of COR-003; • The following herbal medicines are prohibited: St John's Wort, echinacea, gingko, goldenseal, yohimbe, red rice yeast, danshen, silybum marianum, Asian ginseng, schissandra sphenanther, shankhapushi, and Asian herb mixture (Xiao chai hu tang and Salboku-to); • Chronic regular use of topical or inhaled steroids (occasional use is allowed). Steroid use around the time of collection of UFCs (or other cortisol biomarkers) used in monitoring disease should be avoided; • Any other medications used to treat CS or CD due to the lack of data on the safety of COR-003 used in combination with other CS medications.

Duration of the program	Patients are eligible to participate in this program upon completion of the Extended Evaluation Phase in Study COR-2012-01 until COR-003 is commercially available in their country or until the Sponsor or the health authority ends the program due to any reason including but not limited to a refusal to grant marketing authorizations.
Conditions of distribution	The initial drug supply must be requested at least 1 month prior to the anticipated date for a patient's first treatment visit (EAP Baseline or COR-2012-01 M12 Visit) to facilitate the availability of investigational product for the patient at the baseline assessment. COR-003 will be dispensed to patients as a 3-month supply. At each program visit, the Physician will be prompted to document in the patient's medical record and in the online data collection system (including the drug resupply form, as appropriate): categorically classified cortisol levels (and method of assessment) and any AEs, AESIs, SAEs (if not previously reported) and dose increases.
Responsible of the program	The responsible person is: Cortendo AB 900 Northbrook Drive, Suite 200 Trevose, Pennsylvania 19053 **The contact person for program-related enquiries is:** Clinigen Medicine Access department Email: medicineaccess@clinigengroup.com Phone: 065 250 307 **The contact person for regulatory affairs-related enquiries is:** Clinigen Regulatory Affairs department Email: regulatory@clinigengroup.com Phone: +44(0)1283 49 5010
Modalities for the disposal	If a product is not used or only partially used, the treating physician (or pharmacist) may re-dispense all unused medication but only to the designated named patent to whom that product has been allocated. If a patient discontinues the treatment, the treating physician informs Idis. The physician will return all unused supplied COR-003 to Idis warehouse or designee or ensure its destruction at the facility.
The information for registration of suspected unexpected serious adverse reactions	Gastrointestinal disorders: Ileus Hypoglycaemia Investigations: Electrocardiogram QT prolonged Transaminases increased Musculoskeletal and connective tissue disorders: Muscular weakness Neoplasms benign, malignant and unspecified (incl cysts and polyps): Adenocarcinoma of colon

	Colon cancer Metastases to liver