MANAGED ACCESS PROGRAM

Patients with serious or life-threatening diseases or conditions sometimes seek medical products that are not yet approved or available in their country. AveXis’ “Managed Access” addresses this need by making certain investigational or unapproved treatments available to eligible patients.

The AveXis “Managed Access” terminology covers all locally defined pre-approval access mechanisms and programs such as “Compassionate Use”, “Expanded Access”, “Named Patient Supply”, “Special Access Schemes/Programs”, “Autorisations temporaires d’utilisation (ATU)” and others.

Specifically, the following considerations must be met:

- The patient to be treated has a serious or life-threatening disease or condition, and no satisfactory alternative therapy is available, or has exhausted approved treatment options to monitor or treat the disease or condition
- The patient is ineligible for enrollment into or unable to access ongoing clinical trials
- Sufficient information exists to believe the potential benefit of treatment outweighs the potential risk in the context of the disease or condition to be treated
- AveXis has an adequate supply of the investigational product and providing the product will not interfere with ongoing clinical trial(s) or with the overall development program
- The patient meets any other important medical criteria established by the medical experts working on the product development program

The treating physician should contact medinfo@avexis.com for additional information. Each request will be acknowledged within 5 business days, reviewed carefully and fairly by the appropriate AveXis medical experts and every effort made to provide a response promptly once all necessary information is received. Please note that requests will be assessed in consideration of applicable local laws and regulations.