SIFI SpA

Company's external policy on Early Access Programmes

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OUR PROMISE

SIFI's mission is to improve people's lives through meaningful innovation in eye care. SIFI provides ophthalmologists and their patients with a wide range of therapeutic solutions, including medical devices, nutraceuticals and innovative medicines. In this context SIFI aims todevelop effective and safe new medicines with special attention to rare eye diseaseswhere there is a high unmet medical need. To do this, SIFIinvests in development and conducts clinical trials to assess the safety and effectiveness of investigational medicines, which, if established, will help us obtain approvals from regulatory authorities and make the medicines commercially available for patients.

EARLY ACCESS PROGRAMME (EAP) DEFINITION AND CONSIDERATIONS

Yet, there are cases where patients affected by serious sight-threating conditions have not availableon the market comparable, adequate or equally efficacious therapeutic alternatives to treat their disease, or they may be themselves unable or ineligible to participate in clinical trials. In such circumstances, Early Access Programmes (EAP) may represent a real opportunity of treatment for those patients before the product is ready to be launched.

SIFI has adopted the term "EAP," which encompasses investigational medicine access mechanisms in a number of different countries, such as:

- AAC or AP in France
- Expanded Access Programmes (EAP)
- Right to Try in the United States of America
- Compassionate Use programmes (CUP) in Spain and Italy

SIFI will only consider providing investigational medicine to patients pursuant to an EAP under the following circumstances:

1. The initiation of an EAP does not jeopardize SIFI's efforts to advance the clinical research process and gain regulatory approval of the investigational medicine.
2. The EAP is not in conflict with the applicable regulatory guidelines within a particular country.
3. The investigational medicine aims to satisfy anunmet medical need.
4. The safety and efficacy of the investigational medicine in the particular indication must be reasonably established, as determined by SIFI Medical Affairs team, prior to providing the investigational medicine.
5. SIFI has adequate supply of the investigational medicine to satisfy the clinical needs of patients enrolled in Early Access Programmes though avoiding – with reference to the company's supply capabilities - the possible negative impact on the clinical development program.

SIFI will evaluate each product individually to decide on the most appropriate early access mechanism and program type.

SIFI encourages patients to consult their physicians to determine the best course of action on the basis of their specific clinical needs.

MAKING A REQUEST FOR ACCESS TO AN INVESTIGATIONAL MEDICINE VIA AN EAP

When initiating an EAP, SIFI's objectives are to ensure patient safety, serve the patient community with compassion and dignity, and make decisions as ethically and fairly as possible. In addition to the criteria set forth above, requests must meet the following criteria:

Patient

- The patient suffers from a serious, debilitating or life-threatening disease.
- There are no other suitable alternative treatment options available to the patient.
- The patient is not eligible for enrollment in other ongoing Company-sponsored studies for that particular investigational medicine or indication.
- The patient can participate in Early Access Programmes only upon positive evaluation made by the physician.

Physician

- The physician submitting the request must be properly qualified for the management of the considered disease and for administering correctly the investigational medicine and to operate in compliance with the applicable laws and regulations.
- The physician must be qualified for managing and reporting side effects of the investigational medicine.
- The physician must obtain informed consent from the patient for participating in the early access programme and procure the investigational medicine.
- The physician must supervise administration of the investigational medicine in line with Company's defined access criteria (which in some countries may include a protocol for treatment use).
- The request is for an approved use of a product.
- The treating physician reasonably expects that the patient will benefit from the treatment without undue safety risks.

Responsibilities of the physician

Being the investigational medicine not yet approved for the specific therapeutic use, the physician submitting the requesthas the responsibility of evaluate the patient's clinical needs, evaluating the risks and benefits linked to the use of the investigational medicine.

Furthermore, the physician must accept in writing and forward to SIFI the documentation attesting the willingness to comply with the following:

- The investigational medicine must be exclusively used for treating the patients for which the request to Early Access was forwarded.

- Compliance with the regulations in force in each Country must be ensured with regard to availability and investigational medicine supplies to the patient.
- The privacy notice and theconsent form for the processing of personal data within the Early Access Programmesmust be provided by the physician to the patient, who, in order to participate to Early Access Programmes, must accept, sign and return it to the physician.
- The physician has the responsibility of collecting and monitoring the investigational medicine safety profile, and sharing that information with SIFI.

Requests for access must be made by the treating physician by email at (earlyaccess@sifigroup.com) and should include the following details:

1. Date of the request.
2. Physician's name, contact information, address, country and professional qualifications.
3. Name of the investigational medicine and therapeutic indication, including treatment plan.
4. Medical rationale for the request and reason for exclusion from an existing clinical study, if applicable.

All requests received will be carefully reviewed by the Company EAP Governance committee. SIFI commits to respond to requests within five business days of receipt of the request and required medical documentation. A decision will be communicated as soon as possible thereafter. However, the posting of this policy does not guarantee access to Company investigational medicines, even when eligibility criteria are met.

Patients or caregivers seeking access to SIFI investigational medicines should contact their treating physician.

SIFI reserves the right to revise this policy at any time.

DISCLAIMER

The availability of a policy related to EAPs or a request for an investigational medicine made by any individual does not in any way guarantee access to that medicine. SIFI reserves the right to deny access to any investigational medicine for any patient under any circumstances if it deems that doing so is the appropriate course of action after careful consideration. As it relates to charging for an asset via an EAP, SIFI reserves the right to change or modify its decision to charge or not to charge for a particular investigational medicine within a country at any time, if it deems such a decision to be appropriate