Expanded Access to Senhwa Biosciences Investigational Medicines

At Senhwa Biosciences Inc., we are committed to identifying and developing innovative therapies that have the potential to fundamentally change the way patients are treated. Our central philosophy is to unearth validated targets or therapies that could significantly improve treatment but have not yet been properly exploited. Senhwa Biosciences aims to take innovative therapies that could impact the current standard of care and drive them through to clinical Proof-of-Concept.

Our ultimate goal is to provide access to these therapies through marketing authorization. However, before our product candidates might be available through these means, Senhwa Biosciences is committed to carefully considering access to our investigational medicines through expanded access.

The best way to see if a new medicine is sufficiently safe and effective is through clinical studies. Senhwa Biosciences prefers, where possible, to provide patients the opportunity to participate in our clinical studies. However, we recognize not everyone has this opportunity. We will consider early access for patients suffering from serious or immediately life-threatening diseases for which there are no satisfactory alternative treatments available and no chance to enroll in a clinical study.

Our first concern is the safety and well-being of the patient. This is important because these investigational medicines have not completed the normal course of study for the indications under investigation. The patient's treating physician must submit all requests. We will work with this physician to determine whether access to the investigational medicine is best for the patient, which may require more detailed case information to evaluate fully.

Senhwa Biosciences is committed to evaluating all requests in a fair and equitable manner. Decisions are made on a case-by-case basis, and only after considering safety and the possible benefits for the patient based on what we already know about the investigational medicine.

There is no guarantee that every request will be fulfilled; however, each request will be given careful consideration by Senhwa Biosciences whose decisions are final. The requesting physician must agree to obtain appropriate regulatory and ethics committee approvals and comply with regulatory obligations, including obtaining patient consent, patient monitoring, and safety reporting.

Criteria for a Request for Expanded Access

Where there is a possible need for patients to gain early access to a new medicine that is not generally available by prescription, Senhwa Biosciences will consider the need for early access using the following criteria:

- Where it is expected that there is a need for ongoing treatment with one of our investigational medicines, we recognize this must be through normal health services once the investigational medicine is available for prescription. As such, we will only conduct clinical studies and provide early access outside of studies in those countries where we intend to make the investigational medicine available through normal prescription channels after its approval.

- We recognize we must have a minimum level of evidence that the investigational medicine is likely to work before considering early access and must not provide an excessive risk to any patients who may receive the investigational medicine early.

- While addressing this patient's need, we will ensure that if we agree to provide early access to our investigational medicines, there is sufficient investigational medicine available to ensure the supply will not run out for those patients receiving it early or for those patients in our clinical studies. This is because we want to ensure that when providing early access, it does not prevent us from completing clinical studies and regulatory approval, leading to wider access through normal routes of prescription.

- Patient Eligibility:
    - Suffer from a serious or immediately life-threatening disease or condition.
    - Have undergone appropriate standard treatments without success, and no comparable or satisfactory alternative treatment is available or exists to treat the disease or condition.
    - Are ineligible for participation in any ongoing clinical study of an investigational medicine, which includes lack of access due to geographic limitations.

Request for Expanded Access

- **For the Treating Physicians**:
  Please note that requests for expanded access must be made by a physician who:

  - is properly licensed and fully qualified to administer the product.
  - must agree in writing to comply with:
    - Any applicable country-specific legal and regulatory requirements related to providing an investigational product under Expanded Access.
    - Any Senhwa Biosciences requirements in terms of medical criteria, safety reporting, drug supply/use, collection of some relevant information on an ongoing basis while the patient receives the medicine, and protection of intellectual property.

- **For the Patients:**
  If you are a patient with questions concerning access to investigational medicine, please discuss with your treating physician. For more information on our clinical trials that may be recruiting, you can visit our website, or search "Senhwa Biosciences" at www.clinicaltrials.gov.

- **Requesting:**
  Physicians seeking expanded access for patients receiving an investigational product through compassionate use access should submit their requests to expandedaccess@senhwabio.com.
  We will use our best efforts to acknowledge each submitted request within three (3) business days after receipt.

Any early access programs we provide will be in line with the laws and requirements of the country involved.

Senhwa may revise this expanded access policy at any time. This posting will be updated should there be any policy change.