EXPANDED ACCESS POLICY

We continually evaluate the benefit-risk profile of each of our investigational medicines based on evolving clinical data. We recognize that there are circumstances wherein patients with serious or life-threatening diseases have exhausted other comparable or satisfactory alternative therapeutic options and may not be eligible for, or otherwise unable to participate in, one of our clinical trials. In such circumstances, subject to the criteria set forth below, patients may be eligible for Expanded Access to Aquestive’s investigational medicines.

Each investigational medicine under development is different and the fact that one investigational medicine is made available for the treatment of a particular patient does not mean it will be made available in response to other requests on behalf of other patients whose circumstances and medical histories may be different, or that a different investigational medicine will be made available under our Expanded Access policy. Requests will be considered on a case-by-case basis.

All requests for Expanded Access to our investigational medicines outside of a clinical study must satisfy eligibility criteria. Aquestive will evaluate all requests for Expanded Access in a fair and equitable manner. We may not be able to provide Expanded Access in response to all requests received. All requests must be submitted by the patient’s treating physician to Aquestive; we may require more detailed information in order to fully evaluate a request. The requesting physician must agree to obtain or, in Company sponsored Expanded Access programs, assist the Company to obtain appropriate regulatory and ethics committee approvals and to comply with regulatory obligations, including obtaining patient consent, patient monitoring and safety reporting. The request should not include the patient’s name or specific identifying information. Each request will be given careful consideration by Aquestive whose decisions are final. Expanded Access programs may be discontinued under certain circumstances, including if the benefit/risk profile of the investigational medicine has been determined to no longer support further use, and will terminate around the time of the investigational medicine receiving regulatory (i.e., marketing) approval authorizing its general availability for physicians and patients.

Physicians seeking pre-approval access for patients with no alternative treatment options should submit their requests to medinfo@aquestive.com. We regularly monitor this mailbox and will do our best to acknowledge each submitted request in a timely fashion after receipt.