

GENSIGHT BIOLOGICS POLICY ON EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES

Investigational therapy covered by this Policy

GS030 combination product for the treatment of Retinitis Pigmentosa

About Expanded Access

GenSight Biologics is focused on discovering and developing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders. Clinical trials form the foundation of our development programs. These trials are designed to assess the safety and efficacy of investigational medicines. Participation in a clinical trial represents the best way, in a controlled setting, to gain access to an investigational medication. Information about ongoing GenSight-sponsored clinical trials can be accessed by consulting <https://clinicaltrials.gov/>. In some circumstances, a patient may not be able to participate in a clinical trial. Seeking use of an investigational medication under these circumstances is permitted by the FDA and commonly referred to as compassionate use or expanded access. Our policy is intended to comply with U.S. Food and Drug Administration (FDA) requirements for any such use or access.

At this time, given the early stage of development, we are not making our investigational therapy, GS030 combination product, available on an expanded access or compassionate use basis anywhere in the world. Generally, the safety and efficacy data needed to grant expanded access are not available until the initiation of phase 3 clinical trials. For now, participation in our phase 1/2 clinical trial, called PIONEER, is the only way to receive our investigational therapy.

If you are interested in participating in GenSight Biologics clinical trial and would like more information, or if you have any questions about this expanded access policy, please talk to your doctor or contact us <https://www.gensight-biologics.com/form/contact-us/>.

We will continue to evaluate the possibility of expanded access as we advance development of GS030 combination product. As authorized by the 21st Century Cures Act, GenSight Biologics may revise this posted expanded access policy at any time.

The availability of this policy or any revised version shall not serve as a guarantee of access to GS030 by any individual patient.

More information about GenSight Biologics' ongoing clinical trial for Retinitis Pigmentosa, PIONEER, can be found by visiting the link: <https://clinicaltrials.gov/ct2/show/NCT03326336>.

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