Gene Therapy and Genome Editing Policy –Lay Summary

Sanofi believes that gene therapy, including the use of genome editing, has huge potential for the treatment and prevention of many serious human diseases. As such, we fully support the development and use of gene therapies in the non-reproductive cells of the human body when the potential benefit/risk ratio clearly supports their use and when carried out within the legal and ethical frameworks that apply to such work.

Regulatory oversight of gene therapy is critical and helps to ensure the necessary balance between benefit/risk of the potential new treatments. Appropriate regulation provides both oversight and encourages investments in innovation. All marketed gene therapy products should undergo appropriate regulatory review and approval. In order to minimize the regulatory burden, spread the use of best practices in regulatory science, and streamline the process of developing innovative new gene therapy and gene editing-based approaches for treating patients with genetic diseases, efforts should be made to globally harmonize relevant regulations and regulatory decision-making. Where regulatory frameworks for gene therapy and genome editing do not exist, Sanofi encourages global policy makers develop appropriate regulations to enable the discovery and development of novel gene therapies that are both safe and effective.

Sanofi recognizes that many scientific, moral and ethical issues remain to be resolved regarding both the editing of the human reproductive cells and the use of gene therapy in human enhancement. We respect the restrictions placed on such applications of genome editing by some national governments, and encourage the continued societal discussion of these issues as the ethics, science, and a deeper understanding of its benefits and risks, evolve. To this end, Sanofi will not use genome editing techniques to alter the human germline, or use gene therapy for non-therapeutic human enhancement unless and until appropriate ethical, legal and regulatory frameworks are in place.