Position on Human Genome Editing

Background

Breakthroughs in genome editing techniques mark major progress in the life sciences. They foster the development of new therapeutic approaches to fight diseases and contribute to potential societal benefit. At the same time, rapidly progressing human genome editing techniques also pose unprecedented ethical, legal and other social challenges including editing of germline cells that results in heritable change.

As a leading Life Sciences company with a dedicated mission to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products, Astellas is at the forefront of these advances. In partnership with academic research institutes and biotechnology companies, Astellas employees and partners at sites around the world are developing innovative therapeutic approaches by combining an in-depth understanding of the underlying biology of diseases with innovative platforms and treatment modalities which includes genome editing/genome regulation.

Our Position

Genome Editing Standards

Astellas recognizes and supports the ongoing work of the National Institute of Standards and Technology (NIST) Genome Editing Consortium, European Academies' Science Advisory Council (EASAC), U.S. Pharmacopeia, International Organization for Standardization (ISO), World Health Organization (WHO), and other globally authorized organizations to develop global standards for governance and oversight of human genome editing.

Basic & Preclinical Research

Astellas recognizes and supports the premise that basic and preclinical research using genome editing technologies of somatic cells and germline cells should be carried out in compliance with appropriate legal and ethical rules and oversight in order to contribute to health and welfare for patients.

At this time, Astellas will not conduct basic or preclinical research using human germline genome editing.

Clinical Use of Genome Editing

Astellas is committed to research and development for appropriate scientific purposes in compliance with all relevant laws and guidelines. Astellas supports clinical application of genome

editing techniques targeting somatic cells under the oversight of relevant regulatory authorities. However, germline genome editing techniques have not advanced to the point where human clinical trials would be appropriate. Astellas supports the ongoing discussion by governments and international expert advisory committees on the regulation for clinical application of human germline genome editing.
At this time, Astellas will not use human germline genome editing in the clinical setting.

Need for Continued Global Dialogue

Astellas recognizes that there remain many questions awaiting solutions about genome editing, including:

- Ethical, legal and social issues
- Long-term safety
- Value Assessment and Health Technology Assessment (HTA)
- Appropriate payment models to provide access
- Role of intellectual property
- Harmonization of Genetically Modified Organism (GMO) regulation

While each government ultimately has the authority to regulate activities on human genome editing under its jurisdiction, development of global standards on human genome editing is necessary to ensure maximum benefit and minimal risk to human health.

Therefore, Astellas believes governments and the international scientific community should work together to establish norms concerning acceptable uses of human genome editing and to harmonize regulations, in order to discourage unacceptable activities, as identified by international expert advisory committees, while advancing human health and welfare. Astellas also urges that this international dialogue should be inclusive and engage a wide range of perspectives and expertise – including scientists, ethicists, health care providers, patients and their families, policymakers, regulators, research funders, public interest advocates, and industry representatives from across the globe.

References

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