Innovative Regenerative Medicine Technologies and Advances in Regulatory Strategies

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Unprecedented demographic changes are occurring around the world due to the aging of the "baby boom" generation. These changes reflect a dramatic expansion of the elderly segment of the global population, which threatens to have a corresponding impact on national healthcare systems. The envisioned impact of this shift is

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particularly meaningful in Japan, the United States, and certain other developed countries. As we get older, we become more susceptible to a host of aging related diseases and conditions that are more expensive and resource intensive to address, and that also have a substantial impact on patient and family quality of life. This is especially true for certain areas of significant unmet medical need where current standards of care may not provide effective relief or recovery, where patient quality of life may be adversely impacted for years, and where supportive care from family members or institutions represents a substantial cost and resource commitment. While advances in medical treatment have provided meaningful benefits in many areas, current approaches to clinical intervention or supportive care have failed to adequately address some significant areas of unmet medical need, including for the treatment of stroke and other forms of neurological disease and injury, cardiovascular disease, and a host of other areas. Regenerative medicine offers the potential to provide powerful new solutions that could help address major areas of unmet medical need, and could also improve the efficiency of healthcare systems as a whole, while also dramatically improving quality of life for patients and their families. Recent advances in the regulatory area are designed to facilitate this, and could help accelerate a potential technological

revolution in medicine