



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Collaboration

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention described below presents an advancement concerning osteoclast fusion; osteoclasts are responsible for human skeletal remodeling and their dysfunction is a key factor for both rare and common bone diseases. The invention covers methods for modulating osteoclast fusion and bone resorption through the Lupus autoantigen (La) protein. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health, has conducted conceptual *in-vitro* studies and is now seeking potential licensees and collaborators for further development and advancement.

ADDRESSES: Inquiries relating to this licensing and collaboration opportunity should be directed to: Heather Gunas, JD, MPH, Senior Technology Transfer Manager, National Cancer Institute (NCI) Technology Transfer Center, 9609 Medical Center Drive, Room 1E446, Rockville, MD 20850 (*for overnight mail*) or Bethesda, MD 20892 (*for regular mail*), Telephone: (240) 276-5530; Facsimile: (240) 276-5504; E-mail: gunash@mail.nih.gov. A Confidential Disclosure Agreement will be required to receive copies of unpublished information regarding this invention.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are available for licensing: PCT Application No. PCT/US22/018639, filed March 3, 2022, and entitled “La protein as a novel regulator of osteoclastogenesis.” The Lupus autoantigen (La) protein is a master regulator of osteoclasts. The technology involves a novel mechanism for precise regulation of

osteoclastogenesis through the manipulation of surface La protein. The ability of osteoclasts to remodel bone can be modulated by: (1) administering an effective amount of La protein or (2) administering an agent that modulates La protein expression or activity. Current solutions for bone diseases are usually broad-spectrum treatments that either coat the skeletal system or inhibit osteoclast development and these approaches can result in off-target side effects. This technology's approach to regulating osteoclast fusion and osteoclastogenesis by targeting the La protein should bypass many side effects. The technology has been supported by conceptual *in-vitro* data and lead optimization is ongoing; further research and development are required to advance it towards disease-specific preclinical and clinical stages.

Potential Commercial Application: Treatment of common and rare bone diseases, including osteoporosis, Paget's disease of bone, fibrous dysplasia, rheumatoid arthritis, osteopetrosis, osteomyelitis, or metastatic bone disease.

Development Stage: *In-vitro* study completed and lead optimization ongoing.

Dated: September 18, 2023.

Richard U. Rodriguez,

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Technology Transfer Center,

National Cancer Institute.

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