



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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April 22, 2019

James Love
Knowledge Ecology International (KEI)
1621 Connecticut Avenue, Suite 500,
Washington DC 20009

RE: Prospective Grant of an Exclusive Patent License: Use of the CD47 Phosphorodiamidate Morpholino Oligomers for the Treatment, Prevention, and Diagnosis of Solid Tumors (84 FR 1764)

Dear Mr. Love,

Thank you for providing us with your comments in response to the Federal Register Notice of the proposed license to Morphiex Biotherapeutics (Morphiex) by the National Cancer Institute (NCI). We have reviewed and considered all of your comments and the specific recommendations you provided regarding terms to be included in the license related to the pricing of products, the term of exclusivity, the exclusivity and access in developing countries, and the transparency of the licensee's development through annual reporting.

As we previously stated in response to your comments on 83 FR 30448, with respect to your comments regarding the pricing of products in the US and developing countries, the NIH has not included terms related to pricing in its licenses for many years. The reasons for this are well established and are publicly available. Also, with respect to your comments regarding transparency of information regarding clinical trial outlays and research and development costs by the licensee, these are business confidential information that, under the licensing statute cannot be disclosed.

Therefore, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the proposed exclusive license.

Sincerely,
Jaime M. Greene, M.S.
Senior Technology Transfer Manager
NCI Technology Transfer Center