Molecular Targeting Technologies, Inc.

Development Pipeline

CLASS: Therapeutic

NAME: ^{177}Lu-DOTA-EB-TATE (EBTATE)

INDICATION: Neuroendocrine Neoplasms (NEN)

USE: First-in-human studies demonstrated a single low-dose EBTATE treatment appears to be safe and effective in the treatment of NEN. Demonstrated remarkably higher uptake and retention in neuroendocrine neoplasms. EBTATE could be effective with fewer, significantly lower doses than Lutathera®. An EBTATE suitable patient population includes metastatic, SSRT-positive NET patients.

TECHNOLOGY: EBTATE is a peptide receptor radionuclide therapy (PRRT) for the treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors. The drug binds to the somatostatin receptor expressing NET cells and destroys them. 80% NETs overexpress somatostatin receptors (particularly SSTR2).

EBTATE was designed to overcome rapid clearing of Lutathera® by chemically incorporating an Evans Blue moiety in that framework. By increasing residence in albumin, EBTATE substantially lengthens the in vivo half-life increasing the probability of binding between drug and target. That enables fewer, lower doses of the radiotherapeutic.

UNMET NEED: SSAs (Somatostatin Analogs) like Sandostatin, Somatuline and Lutathera that bind to those somatostatin receptors have been used to treat NETs. All have limitations.

PROOF OF CONCEPT: Extensive preclinical and two Phase I studies (50 patients) performed by NIH and Peking Union Medical College Hospital (China).

STAGE OF DEVELOPMENT:

- GLP preclinical, analytical, stability and process development through 2019.
- Phase I/II trial in US beginning 1st Q 2020.

PRINCIPAL COLLABORATORS: NIH & Memorial Sloan Kettering Medical Center

IP: "Chemical Conjugates of Evans Blue Derivatives and their use as Radiotherapy and Imaging Agents (PCT/US2017/054863) filed October 3, 2017, pending

OWNERSHIP: MTTI awarded world-wide-exclusive rights by NIH.

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