



Medikine Presents Preliminary Results of a Single-Dose Phase 1 Healthy Subject Study of MDK-703, a Peptide-Based Mimetic of Interleukin-7 (IL-7)

- *Results presented at the Society for Immunotherapy of Cancer's 37th Annual Meeting describe human data of a product candidate generated by Medikine's proprietary PEPTIKINE™ platform in humans*
- *Intramuscular doses of MDK-703 studied were safe and well-tolerated in healthy subjects and had IL-7-like effects on immune cells in blood*
- *Additional preclinical data presented for MDK-1654, a branched synthetic peptide, demonstrated ability to activate both the IL-7 receptor and the $\beta\gamma\epsilon$ form of the IL-2/15 receptor*

MENLO PARK, Calif., November 10, 2022 /PRNewswire/ -- Medikine, Inc., a biopharmaceutical company developing transformative therapeutics for cancer, autoimmune disorders and infectious diseases using its novel PEPTIKINE™ technology, today announced preliminary safety, tolerability, and pharmacokinetic/pharmacodynamic data from its Phase 1 clinical trial in healthy subjects for its lead program, MDK-703, a peptide-based interleukin-7 (IL-7) mimetic with an extended half-life.

The data, which were presented during the Society for Immunotherapy of Cancer 37th Annual Meeting (SITC 2022), demonstrated that MDK-703 was well-tolerated and safe after a single intramuscular administration at doses of both 10 and 30 ug/kg. Additionally, MDK-703 demonstrated drug exposure in blood consistent with high bioavailability and, as expected, produced extended elevation of CD8 and CD4 T cells compared to baseline with minimal effects on regulatory T cells (Treg) and natural killer (NK) cells. Further analysis showed that MDK-703 produced expansion of memory T cells, specifically CD8 and CD4 T-stem cell memory (Tscm), T-central memory, and T-effector memory cells, in blood.

“We are encouraged by the early trial results of MDK-703, which in this study passed the crucial proof-of-pharmacology threshold of expanding T cell populations and, most importantly, demonstrated a unique proliferative effect on the Tscm subpopulation, which is essential for T cell survival, renewal, and the avoidance of exhaustion,” said Dr. Joseph Leveque, president and chief medical officer of Medikine. “We anticipate this T cell ‘stemness’ effect associated with MDK-703 will induce a potent and persistent anti-tumor response in cancer patients and look forward to further investigating its clinical utility in solid tumors beginning early next year.”

A second poster presentation detailed preclinical results in peripheral blood monocytes (PBMCs) from healthy donors for MDK-1654, Medikine's dual-acting agonist that incorporates both IL-7 and non-alpha IL-2/15 PEPTIKINES. This is the first demonstration of a synthetic peptide with agonist activity for two clinically relevant cytokine receptors.

In addition to activating both the IL-2/15R β γ c and IL-7R α γ c signaling pathways, MDK-1654 expanded all memory T cells, including CD8 Tscm. It also exhibited additive and complementary effects of IL-2/15R β γ c and IL-7R α γ c signaling among various blood immune cell populations, specifically Tscm, γ δ T cells, and NK cells. T cells and NK cells are important cells that have a high cytotoxic, tumor-killing, and anti-tumor capacity.

Together, the combined actions of MDK-1654 suggest it could drive deep and durable anti-tumor responses in cancer by activating cells involved in both the adaptive and innate immune systems.

"Medikine is employing a unique and versatile drug discovery platform to generate modular cytokine-mimetic 'PEPTIKINES' that are engineered with distinctive features and optimized therapeutic attributes not found in naturally occurring cytokines," said Ronald W. Barrett, Ph.D., chief executive officer and chairman of the board of Medikine. "To our knowledge, MDK-703 is the first peptide-based molecule that has been shown in humans to emulate the activity of a cytokine that works through a hetero-dimeric receptor. As such, it serves as important validation of Medikine's PEPTIKINE technology. We look forward to investigating MDK-703 in solid tumors both as monotherapy and in combination with a PD-1 inhibitor and expect to enroll the first patient in the start of these studies in the first quarter of 2023. We also plan to advance our IL7/IL2 Dual PEPTIKINE program to selection of an IND candidate in 2023."

Both poster presentations are now available on the Medikine website at www.medikine.com.

ABOUT MDK-703

MDK-703 is an investigational biologic interleukin-7 (IL-7) mimetic consisting of an IL-7 PEPTIKINE fused to an immunoglobulin Fc-domain that was discovered using Medikine's platform technology.

IL-7 is a cytokine critical for the development and maintenance of T cells, including enhancing generation, function, and survival of memory T cells. By emulating these effects of IL-7 on T cells, MDK-703 may enhance the rate, depth, and durability of clinical responses, alone or in combination with other immune-based therapies. Additionally, MDK-703 has the beneficial property that it may not generate anti-drug antibodies (ADAs) that neutralize native IL-7, an issue previously observed with IL-7 agents that have been studied in humans.

Medikine has presented preliminary results from a Phase 1 study of MDK-703 in healthy volunteers and plans to investigate MDK-703 in solid tumors both as monotherapy and in combination with a PD-1 inhibitor in clinical studies in 2023.

ABOUT MEDIKINE

Medikine is a biopharmaceutical company with a mission to transform the discovery of oncology, autoimmune disorder and infectious disease therapeutics by employing a versatile drug discovery platform that generates modular “PEPTIKINES” - peptide mimetics of cytokines that are smaller in molecular size than, and structurally unrelated to, the natural cytokines they emulate. These PEPTIKINES are engineered for low immunogenicity and are readily amenable to the incorporation of targeting and other pharmacological features.

Medikine’s lead candidate, MDK-703, currently in a Phase 1 clinical trial in healthy volunteers, is an IL-7 PEPTIKINE fused to an immunoglobulin Fc-domain. MDK-703 emulates the beneficial properties of IL-7, a cytokine critical for maintenance of T cell responses.

For more information, please visit www.medikine.com.

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