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Angimmune's Investigational Cutaneous T-cell Lymphoma Disease Treatment A-dmDT390-bisFv(UCHT1) or Resimmune[®] Granted FDA Fast Track Designation

ROCKVILLE, MD, September 9, 2016 – Today Angimmune announced that A-dmDT390-bisFv(UCHT1) or Resimmune[®], its investigational treatment for cutaneous T-cell lymphoma (CTCL), was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). The designation is for the most common form of cutaneous T-cell lymphoma, mycosis fungoides.

Angimmune is a clinical stage biotechnology company investigating the use of anti-CD3 immunotoxin therapy in the treatment of T-cell related diseases, metastatic melanoma, and autoimmune diseases.

“CTCL is a devastating, disfiguring and ultimately fatal disease, and identifying more effective therapies, especially in early stages of the disease, has been an elusive goal,” said David Neville, M.D., president and chief scientific officer, Angimmune. “Results from our Phase I trial demonstrated a particularly robust response among certain patients with early-stage disease, and the randomized Phase II trial is designed to further explore this potential therapeutic benefit.”

The application was based on promising results seen among a group of high responders in the Phase I study with earlier stage disease, and complete responses were documented between 4 to 6 years, post a single 4-day treatment. Results were published in *Haematologica* (Frankel A.E., Woo J.H., Ahn C., Foss F.M., Duvic M., Neville P.H., and Neville D.M., 2015. Resimmune-an anti-CD3 ϵ recombinant immunotoxin induces durable remissions in cutaneous T cell lymphoma patients. *Haematologica*. 100: 794-800). The Phase II study will be run at 17 U.S. centers where the objective is to document the incidence of complete responses compared to oral vorinostat, in a randomized 2-arm trial after a maximum of 12 months of treatment for subjects with stage IB/IIB mycosis fungoides with mSWAT < 50 who have never had lymphoid disease or a prior bone marrow / HSCT transplant.

About CTCL

CTCL is a form of cancer impacting approximately 3,000 new patients per year in the U.S., with an estimated prevalence between 20,000 and 30,000. CTCL initially affects the skin and can then progress to the blood, lymph nodes and other parts of the body, and causes T-cells -- a type of white blood cell that plays a critically important role in a person's immune response -- to multiply at an abnormal and uncontrollable rate. Systemic therapies for advanced CTCL include radiation and various forms of chemotherapy. However, the disease does not always respond to these therapies.

About Resimmune

Resimmune is the result of years of research into the role of immunotoxins in the treatment of diseases involving T-cells. Resimmune[®] is an Anti-CD3 Immunotoxin that

targets and transiently depletes a high percentage of T-cells in the body, both malignant and normal. Researchers believe that the high rate of T-cell depletion may “reset” a patient’s immune system, leading to immunomodulation. The safety and efficacy of Resimmune has not been established.

Investigating Resimmune’s Immunomodulation

Resimmune transiently depletes between 2-3 logs of T-cells by day 5, which are then repopulated via Homeostatic Proliferation during days 6-38. In the Phase I trial, responding patients progressed from Partial Responses (PR’s) at day 38 to Complete Responses (CR’s) over the course of 6-36 months, after a single 4-day treatment (serum half-life ~45 minutes). This indicates an immune system response that is not dependent on the presence of the active drug. Mouse solid tumor models have consistently shown a profound anti-tumor effect following lymphopenic induced homeostatic proliferation (1-3). The mechanism has been ascribed to the marked increase in central memory T-cells having an activating phenotype, CD44⁺ CD62L⁺ Ly6c⁺. These cells are readily functional in vitro with a strong capacity to secrete INF γ and IL-2 and to lyse target cells on antigen recognition (2,3). In the course of treating patients with cutaneous T-cell lymphoma with the T-cell depleting agent Resimmune, we noted long-term anti-tumor effects. This 4-day treatment was associated with homeostatic proliferation and a 20-fold increase in CD8⁺ central memory T-cells with activation markers CD45RA^{-/low} CD27⁺, similar to the results observed in mice. Angimmune’s phase II studies will further document Resimmune’s method of action.

About Angimmune

Angimmune LLC is a Rockville, MD-based biotechnology company focused on researching the role of immunotoxins in the treatment of T-cell related diseases, including blood and skin cancers and certain autoimmune disorders. Angimmune was co-founded by David Neville, M.D., a pioneer in immunotoxin research. Dr. Neville co-founded Angimmune after a nearly 50-year career at the National Institutes of Health (NIH), where he was Chief of the Section on Biophysical Chemistry in the Laboratory of Molecular Biology. In addition to Dr. Neville, Angimmune’s co-founders include Yuan-Yi Liu, Ph.D. and Jung-Hee Woo, Ph.D.

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References

1. Dummer et al., J Clin Invest. **110**, 185, (2002)
2. Brown et al., J Immunol. **177**, 4521 (2006)
3. Kaiser et al., Ca Immunol Immunother. **62**, 503 (2013)

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