Aminex Therapeutics

Empowering the Immune System Against Cancer

Executive Summary

1/11/2022

Overview

Aminex Therapeutics is a clinical stage drug development company seeking FDA approval for a first-in-class cancer immunotherapy treatment – AMXT 1501 plus DFMO. Phase 1 safety trial results in 42 solid tumor cancer patients have thus far demonstrated several patients experiencing signals of positive tumor responses including duration of stable disease and clinical benefit. Some patients experienced temporary gastrointestinal (GI) toxicity events (more detailed trial outcomes are discussed below).

Aminex's goal is to demonstrate clinical efficacy with our drugs that is consistent with positive results in numerous mouse model tumors, documented in eight published scientific studies. As further validation of our drug development progress, two distinguished, non-profit organizations have indicated strong interest in performing pediatric trials using Aminex's drug combination. One of these non-profits achieved extraordinary results in animal studies of children's rare cancers: neuroblastoma and DIPG.. These trials would be performed at their own expense to address these high-mortality childhood cancers.

The Opportunity

Aminex's investigational treatment is targeting cancer's dependence on polyamine production. These polyamines and their metabolism are well recognized in the scientific community as being increased by cancer, including by the oncogenes Myc and Ras -- two oncogenes that have been termed 'undruggable' by the field. Polyamines in the tumor microenvironment shield cancer from the body's natural immune defense system. In so doing, the cancer hides from the immune attack. Data to-date suggest that Aminex's drugs remove these polyamine 'cloaking' compounds, unleashing the body's natural immune attack against the cancer. This release of the immune system appears to be achieved by our

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two drugs depleting the cancer cell's polyamine biosynthesis (manufacturing) and the uptake of polyamines (transport) from the blood.

The Aminex Solution – Current Status

Aminex has demonstrated that its drugs unlock the anticancer potential of polyamine depletion with its patented drug AMXT 1501, a potent polyamine uptake inhibitor, combined with DFMO, a polyamine biosynthesis inhibitor. Multiple animal studies appear to indicate that these two drugs, in combination, enable the immune system to recognize the cancer, actively reducing the tumor burden, and clearing the cancer from the body. Furthermore, when Aminex's treatment is halted and more cancer cells are introduced into the animal, tumors do not grow back due to the immune system's memory. Based on the pronounced activity shown against tumors in published studies, Aminex believes its drugs could show effectiveness against 60-70% of all solid cancers. We believe AMXT 1501 plus DFMO will enable treatment of 'undruggable' Myc and Ras-driven tumors. Moreover, because of the ability of AMXT 1501 plus DFMO to unleash the natural immune reactivity against cancer, we believe our treatment will also provide improved activity for other immunotherapies used in oncology.

Aminex Achievements and Vision for Success

42 solid-tumor patients (as of 12/2021) have been treated as part of our Investigational New Drug (IND) dose-escalation clinical trial with AMXT 1501 plus DFMO. These patients primarily have stage 4 cancer (metastatic) and have either relapsed or not responded to prior treatments before entering the Aminex trial. From patient scans and blood studies, we see indications that we are now delivering enough AMXT 1501 to engage our drug's target. Animal tumor models highlighted the pronounced ability of AMXT 1501 to associate with tumors, showing the drug as much as 900 times higher in the tumor versus background blood levels. Patients in our next cohorts will be treated with increasing amounts of our second drug DFMO, to demonstrate, in humans, the results we observed in eight different animal models.

We are moving forward based upon the knowledge gained from our recent trials. Temporary GI toxicity experienced by some patients has resulted in a revision of our drugs' dosing formulation and moving one drug from oral to intravenous (IV) dosing. One patient

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was designated "partial response" as their cancer reduced more than 30% at the end of their eighth 28-day treatment cycle as compared to their baseline cancer measurements. Most patients, to date, have been at doses lower than the anticipated final recommended Phase 2 dose. A key milestone in the next few months is to escalate the second drug, using IV dosing, to safely achieve the dual drug recommended Phase 2 dose level. We anticipate this will resolve the GI toxicity, but must confirm this.

Intellectual Property

Aminex Therapeutics owns patent rights to AMXT 1501 dicaprate until March 20, 2037.

Opinions of Third Party Collaborators

- Treatment with AMXT 1501 was found to re-sensitize DIPG cells to DFMO leading to what Associate Professor Ziegler said, *"was a spectacular response in animal models, with a significantly increased survival and minimal toxicity (side effects)."* *(Feb. 2021 press release:* Sydney Researchers Identify Potential New Drug Treatment Developed by Aminex Therapeutics for Fatal Childhood Cancer)

- *"This exciting new treatment approach warrants clinical investigation in children with MYCN-driven high-risk neuroblastoma, and potentially other cancers as well,"* said Professor Michelle Haber AM, Executive Director, and Professor Murray Norris AM, Deputy Director, Children's Cancer Institute, Australia.
(Jan. 2019 press release: International Research Team Led by Australian Scientists Discover a Potential Way to Treat and Prevent Cancer in Children with Neuroblastoma)

Following the results from mouse models of pediatric tumors, several independent non-profit organizations have sought to partner with Aminex to conduct human pediatric trials, at the non-profits' expense. Aminex would provide our drug compounds (free of charge) and collaborate on blood/biopsy analysis. **The University of Ohio Nationwide Children's Hospital**, and the **Children's Cancer Institute of Australia** are currently working together to conduct clinical trials in children for the rare childhood cancers DIPG and Neuroblastoma. While there is a lower market opportunity in treating rare childhood cancers, finding a cure for these diseases would represent a great service to humanity. There is the opportunity of

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receiving an FDA "Priority Review Voucher" which has been valued at up to $350 million since established in 2012, with a current estimated value of $100 million if the drug is first approved for either of these rare children's cancers before adult approval.

Competition

We are not aware of any other clinical trials of competitive polyamine depletion approaches. Aminex's goals are to show clinical efficacy of our two-drug combination on its own, then build upon its immunomodulatory actions as a first-in-class (unprecedented) approach individually, and in combination with successful immunotherapies currently on the market. Currently available immunotherapy drugs offer tremendous benefit to patients, yet only a modest fraction of patients respond leaving a large unmet medical need. Those patients who do respond are, in essence, cured. We aim to greatly improve this fraction of cured patients.

Financial Profile

Aminex' development of a novel approach to treating cancer has consistently followed a low-cost, accelerated plan to speed our clinical trials to the completion of Phase 1.

At the conclusion of the 2021 Series C fundraising round (of up to $6MM), Aminex will have raised and spent less than $29 million through planned completion of Phase 1 and Phase 1B/2A clinical trials. All Aminex funding has come from fewer than 200 individual investors, and no venture capital, family offices or other similar funding. This cost-effective approach has been accomplished by avoiding bricks-and-mortar expenditures, and by outsourcing technical work to top industry labs, manufacturing companies and consultants. The peak monthly burn rate has consistently been under $400,000 per month for the clinical trial period. Fundraising has been structured to achieve specific milestones over a defined and limited period, and Aminex has zero debt.

The founders and staff of Aminex are highly focused and passionate towards achieving the goal of demonstrating safety and efficacy in clinical trials. Aminex aims to demonstrate in patients what we have already shown in animal studies. It is also worth noting that Aminex's CEO and its Board of Directors receive no salary.

Aminex Therapeutics ➡ https://aminextx.com/

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Leadership Team

(see Aminex website (www.aminextx.com) for additional bio information)

Aminex has attracted an exceptional team of staff, board members and advisors, experienced in developing and taking drugs to market, conducting, and managing clinical trials, and managing companies to great profitability and shareholder value. Additionally, all of these recruits have been with Aminex for years, with growing enthusiasm.

Jim Skaggs -- Chairman, Chief Executive Officer: Executive leadership for Apollo Lunar Landing Program and multiple high- technology companies, Fortune 100 Fastest Growing and Fortune 500 Industrial Companies

Mark Burns, PhD -- Director, Founder, President & Chief Scientific Officer: Internationally recognized leader in drug discovery; expert in medicinal chemistry and inventor of Aminex Therapeutics drug candidates

Kathy Fosnaugh, PhD -- Director of Program Management: 20+ years experience in Biotech R&D in cancer biology

Nicole Gallegos, MBA -- Director of Clinical Operations: 20+ years experience in clinical operations and data management

Greg Coulter, PhD -- Director of CMC/Product Development: 20+ years GLP, cGMP, GCP product development experience.

Jeff Judson -- Vice President, Strategic Planning: 30+ years experience in business development, public and regulatory policy, communications, and project management.

<u>Scientific Advisors</u>

Stephen B. Baylin, MD -- Professor, Cancer Research Program and Initial Clinical Cancer Studies on DFMO (Johns Hopkins Medical School)

Michael Palfreyman, PhD, DSc, MRPharmS **--** Four decades leadership in drug discovery and development including major Pharma and Biotech Companies with oversight of 25 INDs and NDAs

Paul J. Schechter, MD, PhD -- Multiyear experience as Chief Medical Office in Pharma and Biotech. Led IND and NDA for DFMO in cancer and trypanosomiasis. Polyamine and DFMO Clinical Expert (NIH, MMD, Sanofi, Fujisawa, Hybridon, MacroChem, Nucryst).

Philippe Bey, PhD -- Past Chief Scientific Officer, SVP R&D, Pharma and Biotech. Inventor of DFMO

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Robert Lewis, MD -- Consulting Professor, Stanford. Physician-scientist, Harvard, Syntex, Aventis. Immunology-Cell Biology

Key Contacts for More Information

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