Celldex Therapeutics Inc.

Fact Sheet

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CELLDEX THERAPEUTICS

QUICK REFERENCE

Celldex Therapeutics Inc.
NASDAQ: CLDX

Website: **www.CELLDEX.com**

BUSINESS SUMMARY

Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer.

Many of our clinical programs seek to leverage the power of the immune system's response by combining therapeutic approaches to maximize their potential. Key to this strategy is our ability to understand our own asset base while also identifying promising external technologies that will complement it. In 2005, Celldex was spun out of the New Jersey based biopharmaceutical company Medarex (acquired by the Bristol-Myers Squibb Company) and, in connection with this transaction, Celldex retains the rights to obtain exclusive commercial licenses to proprietary monoclonal antibodies raised against certain antigens utilizing the Medarex UltiMAb technology platform. Since its inception, Celldex has also acquired five companies, folding in five assets, and in-licensed/purchased an additional two assets.

PIPELINE

CDX-0159 – A Potent KIT Inhibitor

CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. KIT is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells. In certain inflammatory diseases, such as chronic urticaria, mast cell activation plays a central role in the onset and progression of the disease.

CDX-1140 – A Differentiated CD40 Agonist Antibody

CDX-1140 is a fully human antibody targeted to CD40, a key activator of immune response which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays.

CDX-527 – A Bispecific Antibody Combining PD-1 Blockade and CD27 Costimulation

CDX-527 is the first candidate from Celldex's bispecific antibody platform. It uses Celldex's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 costimulation with blockade of the PD-L1/PD-1 pathway to help prime and activate anti-tumor T cell responses through CD27 costimulation, while preventing PD-1 inhibitory signals that subvert the immune response. Preclinical data demonstrate CDX-527 is more potent than the combination of anti-PD-L1 and anti-CD27 antibodies in T cell activation and anti-tumor activity. In addition, CDX-527 exhibits an antibody-like pharmacokinetic profile without concerning toxicity in preclinical models. Prior clinical data with Celldex's CD27 antibody as monotherapy and in combination with PD-1 inhibitors, supports combining these pathways in patients with cancer. The Company believes that the potential for CDX-527 will include both monotherapy and combination studies with other immunotherapies or conventional cancer treatments.

CONTACT INFORMATION

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Recent Press Releases *(Headline and Excerpts)*

Celldex Presents Positive Data on Symptom Control and Quality of Life Measurements that Further Support CDX-0159 Clinical Benefit in Phase 1b Study in Chronic Inducible Urticaria at EADV 2021

- Rapid and sustained improvement in urticaria control after single dose of CDX-0159 -
- Greatly improved patient quality of life and reduced disease impact -
- Data further support 95% complete response rate to provocation testing -

Sept. 29, 2021 -- Celldex Therapeutics, Inc. announced positive data on measurements of symptom control and quality of life from the Company's ongoing, open label Phase 1b clinical trial of CDX-0159 in patients with antihistamine refractory cold urticaria and symptomatic dermographism, the two most common forms of chronic inducible urticaria. These diseases, which are often severe and debilitating, can significantly impact patients' lives. CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity.

A single dose of CDX-0159 (3 mg/kg) resulted in a rapid and sustained improvement in urticaria control and greatly reduced disease impact on quality of life, as measured by the Urticaria Control Test (UCT) and Dermatology Life Quality Index (DLQI). These data build on the previously reported results which demonstrated rapid, profound, and durable responses in 100% of patients with 95% achieving complete response, as assessed by provocation testing (TempTest® and FricTest®).

These data were presented by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité – Universitätsmedizin, during an e-poster session (#P0368) as part of the European Academy of Dermatology and Venereology (EADV) 2021 Virtual 30th Congress.

Celldex Announces Initiation of CDX-0159 Subcutaneous Formulation Study

Sept. 13, 2021 -- Celldex Therapeutics, Inc. announced that the first cohort has been dosed in the Phase 1 study of the subcutaneous formulation of CDX-0159 in healthy volunteers. CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. The Company intends to utilize the subcutaneous formulation of CDX-0159 in its Phase 2 program in chronic urticarias, planned for initiation in the first half of 2022. Celldex is currently studying an intravenous formulation of CDX-0159 in Phase 1 studies in chronic spontaneous and chronic inducible urticarias and will initiate a third intravenous study in prurigo nodularis later this year.

The randomized, double-blind, placebo-controlled Phase 1 study will evaluate single ascending doses of CDX-0159 administered subcutaneously in healthy volunteers. Thirty two subjects will be enrolled across four dosing cohorts (50 mg, 150 mg, 300 mg and 600 mg) with 8 subjects in each cohort (6 active; 2 placebo). Subjects will be followed for 12-weeks after dosing. The primary endpoints of the study are safety and tolerability; secondary endpoints include pharmacokinetics, pharmacodynamics (circulating tryptase and stem cell factor) and immunogenicity. For additional information on this trial (NCT05031624), please visit www.clinicaltrials.gov.

Celldex Therapeutics Presents Positive Data from CDX-0159 Phase 1b Study in Chronic Inducible Urticaria at EAACI 2021

- 95% complete response rate after single dose of CDX-0159 -
- Rapid, profound and durable responses offer patients opportunity for quick, lasting, meaningful relief -
- Median duration of response 77+ days in Cold Urticaria and 57+ days in Symptomatic Dermographism -
- Serum tryptase and skin mast cell depletion mirror clinical activity -
- Favorable safety profile -
- Company to host webcast conference call on Monday, July 12 at 8:15 a.m. ET -

July 09, 2021 -- Celldex Therapeutics, Inc. announced updated data from the Company's ongoing, open label Phase 1b clinical trial of CDX-0159 in patients with antihistamine refractory cold urticaria and symptomatic dermographism, the two most common forms of chronic inducible urticaria. These diseases, which are often severe and debilitating, can significantly impact patients' lives. CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity.

All 19/19 (100%) patients who received a single full dose of CDX-0159 experienced a clinical response to provocation testing. 18/19 (95%) experienced a complete response and 1/19 (5%) experienced a marked partial response. Responses were rapid, profound, and durable and correlated with a depletion of skin mast cells. CDX-0159 was generally well tolerated. These data were presented by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité – Universitätsmedizin, in Berlin during a late-breaking poster discussion session (#1046) as part of the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2021.

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