Opexa Therapeutics, Inc.
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Opexa Therapeutics Overview

Opexa Therapeutics, Inc. (NASDAQ:OPXA) is a publicly traded biotechnology company dedicated to the development of patient-specific immunotherapies for the treatment of autoimmune diseases, including multiple sclerosis. **Tcelna™** is an autologous T-cell immunotherapy being developed for the treatment of multiple sclerosis (MS), and is specifically tailored to each patient's immune response profile to myelin. **Tcelna™** is designed to reduce the number and/or functional activity of specific subsets of myelin-reactive T-cells (MRTC) known to attack myelin. **Tcelna™** is manufactured using **ImmPath™**, Opexa Therapeutics' proprietary method for the production of an autologous T-cell product, which comprises the collection of blood from the MS patient and the expansion of MRTC from the blood. On completion of the manufacturing process, MRTC are formulated and attenuated by irradiation before returning the final product to the clinical site for subcutaneous administration to the patient, with the express purpose of inducing a regulatory immune response to impede immunity to myelin.

Tcelna™ *(imilecleucel-T)*

- Opexa's leading product candidate;
- Possesses a unique mechanism of action that combats the demyelination of the nerve fibers in the central nervous system, the underlying cause of MS;
- Opexa has received Fast Track designation by the U.S. Food and Drug Administration for **Tcelna™** in Secondary Progressive Multiple Sclerosis.

Abili-T: A Phase IIb Clinical Trial for Secondary Progressive Multiple Sclerosis

Abili-T Study Overview

Protocol Title	A Phase 2 Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of **Tcelna™** in Subjects with Secondary Progressive Multiple Sclerosis (SPMS)
Study Design	Multi-center, randomized, double-blind, placebo-controlled, 2-arm, 2-year, parallel-group study of Tcelna™ compared with placebo in subjects with gradual increasing disability with or without superimposed clinical relapses in the preceding two years
Tcelna™ Treatment	**Tcelna™**, 30-45 x 10^6 total cells in 2.0 mL subcutaneous (SubQ) injection, consisting of non-replicating, autologous, activated, myelin-reactive $CD4^+$ and/or $CD8^+$ T-cells
Regimen	Subjects will be treated in two annual courses consisting of 5 treatments per year. Subjects receive SubQ injections at Weeks 0, 4, 8, 12 and 24. Upon the completion of year one, subjects will be retreated with a second course following the same treatment schedule.
Study Duration	Subjects will receive 6 months treatment with 6 months clinical evaluations for each year of study participation. Total study duration is approximately 26 months (6-8 week screening/manufacturing period followed by 2 year treatment/evaluation period)
Location	30-35 Sites in the United States and Canada
Subject Population	Subjects 18-60 years old, diagnosis with SPMS (defined as relapsing-remitting disease with recent progression in MS-related neurologic deficits independent of relapses within the previous 2 years) with an EDSS score of 3.0-6.0 and the presence of myelin-reactive T-cells
Number of Subjects	180 subjects with 1:1 randomization, **Tcelna™**: placebo
Efficacy Measures	Primary Efficacy Endpoint: Percentage of whole brain volume change from baseline at two years Numerous additional assessments of clinical and radiological endpoints will be conducted in this study to determine their ability to detect treatment effect in the SPMS population.

See www.clinicaltrials.gov and search "**Abili-T**" for more information, including a list of participating sites.

Abili-T Site Locations:		United States and Canada	
Site #	Site Name	PI City	PI State
101	University of Ottawa	Ottawa	ON
102	Montreal Neurological Institute and Hospital	Montreal	QC
103	Pasqua Hosptial	Regina	SK
001	Providence Saint Vincent Medical Center	Portland	OR
002	Baylor College of Medicine	Houston	TX
003	University of Miami	Miami	FL
004	Swedish Neuroscience Institute	Issaquah	WA
005	Associates in Neurology, PC	Lexington	KY
006	Axiom Clinical Research of Florida	Tampa	FL
007	Shepherd Center, Inc.	Atlanta	GA
008	HOPE Research Institute, LLC	Phoenix	AZ
009	Consultants in Neurology Ltd.	Northbrook	IL
010	Integra Clinical Research, LLC	San Antonio	TX
011	University of Pennsylvania	Philadelphia	PA
012	State University of New York	Stony Brook	NY
013	Josephson Wallack Munshower Neurology, PC	Indianapolis	IN
014	University of Kansas Medical Center	Kansas City	KS
015	Island Neurological Associates, PC	Plainview	NY
016	Alta Bates Summit Medical Center	Berkeley	CA
017	Neurological Services of Orlando	Orlando	FL
018	Fletcher Allen Health Care	Burlington	VT
019	Medford Medical Clinic, LLP	Medford	OR
020	Neurology Specialists, Inc.	Dayton	OH
021	Collier Neurologic Specialists, LLC	Naples	FL
022	Saint Elizabeth's Medical Center	Boston	MA
023	Carolinas HealthCare System	Charlotte	NC
024	Central Texas Neurology	Round Rock	TX
025	Hampton Roads Neurology	Newport News	VA
026	Northwest NeuroSpecialists, PLLC	Tucson	AZ

Abili-T

A Phase IIb Clinical Trial for Secondary Progressive MS Patients

- Fast Track designation by FDA -

Opexa Therapeutics Mission Statement

To lead the field of precision immunotherapy by aligning the interests of patients, employees and shareholders

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OPEXA THERAPEUTICS

Dosing Timeline		Year 1								Year 2							
Determine Eligibility		Dosing period-year 1					Follow-up			Dosing period-year 2					Follow-up		
Determine subject eligibility	Obtain blood procurement for manufacturing	wk 0	wk 4	wk 8	wk 12	wk 24	wk 36	wk 40	wk 42	wk 52	wk 56	wk 60	wk 64	wk 76	wk 88	wk 104	
		X	X	X	X	X				X	X	X	X	X			