OPEXA THERAPEUTICS

Company Profile

Opexa Therapeutics (NASDAQ:OPXA) is a biotechnology company dedicated to the development of patient-specific immunotherapies for the treatment of autoimmune diseases. The company's lead product candidate has the potential to address the significant unmet medical needs of the large multiple sclerosis (MS) patient population.

Opexa's lead therapy, Tcelna™, formerly known as Tovaxin®, a personalized T-cell immunotherapy for the treatment of multiple sclerosis (MS), is specifically tailored to each patient's immune response to myelin. **Tcelna** possesses a unique mechanism of action that combats the demyelination of the nerve fibers in the central nervous system, the underlying cause of MS.

In multiple previously conducted clinical trials, **Tcelna** has demonstrated one of the safest side effect profiles for any marketed or development MS therapy, as well as important efficacy signals indicating the therapy has the potential to be effective in the treatment of both Secondary Progressive MS (SPMS) and Relapsing Remitting MS (RMSS) patients.

Tcelna is manufactured in-house at Opexa's cGMP (Good Manufacturing Practice) facility using its proprietary process, **ImmPath**™. This process generates sufficient **Tcelna** doses for one annual treatment cycle from a single unit of whole blood with attractive Cost of Goods at this stage of development.

Clinical Development: Opexa, which has received Fast Track designation by FDA for **Tcelna** in SPMS, recently initiated its Phase IIb trial, Abili-T, in this indication. In addition, Opexa has completed formal *End of Phase II* meetings with the FDA and has received support to move forward with pivotal Phase III clinical trials in RRMS.

"Abili-T"
A Phase IIb Clinical Trial
for Secondary Progressive MS Patients

The Abili-T trial is a randomized, double-blind, placebo-controlled study of **Tcelna** in SPMS patients. 180 patients are expected to be enrolled at approximately 30 leading clinical sites in the US and Canada and will be treated and assessed for two years.

Opexa's proprietary web-based system, **ImmForm**™ will be used to manage patient scheduling and product flow throughout the study.

See www.clinicaltrials.gov for more information including a list of participating sites.

Abili-T Overview

The Abili-T trial is a randomized, double-blind, placebo-controlled Phase IIb study designed to determine the efficacy and safety of Tcelna in subjects with SPMS.

The primary efficacy outcome is the percentage of brain volume change (atrophy), as measured on a 24 month MRI and calculated by a central MRI reader.

Secondary outcome measures include:

- **Sustained disease progression, as measured by the Expanded Disability Status Scale (EDSS)**
- **Development of black holes**
- **Change in cortical grey matter volume**
- **Changes in disability, as measured by EDSS and Multiple Sclerosis Functional Composite (MSFC)**
- **Annualized relapse rate (ARR)**
- **Cognitive changes, measured by Symbol Digit Modality Test**

The study will also explore other endpoints:

- **Quality of life, measured by Multiple Sclerosis Quality of Life Inventory (MSQLI)**
- **Assessments by the Magnetization Transfer Ratio (MTR)**
- **Changes in T-regulatory cell repertoire and function**

Abili-T Key Entry Criteria

- **Subjects aged 18 to 60 years**
- **Presence of Myelin Reactive T-cells at screening**
- **SPMS with evidence of progression independent of relapses in the last 2 years**
- **EDSS score from 3.0 to 6.0, inclusive**
- **Adequate washout from other therapies:**
  - **60 days from corticosteroid use**
  - **30 days from beta-interferon or glatiramer acetate use**
  - **One year from mitoxantrone, teriflunomide, fingolimod, natalizumab and methotrexate use**