

OPEXA THERAPEUTICS, INC.

FORM FWP

(Free Writing Prospectus - Filing under Securities Act Rules 163/433)

Filed 01/28/15

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
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OPEXA THERAPEUTICS

Issuer Free Writing Prospectus
Filed Pursuant to Rule 433
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January 28, 2015



Precision Immunotherapy®

Opexa Therapeutics, Inc.

NASDAQ: OPXA

January 2015
The Woodlands, TX

Free Writing Prospectus Statement

- This presentation highlights basic information about us and the offering. Being a summary document, this slide deck does not contain all the information that you should consider before investing.
- We have filed a registration statement (including a preliminary prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein) and other documents, including the Company's Form 10-Ks and Form 10-Qs, that we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting the "Search EDGAR" section on the SEC web site at <http://www.sec.gov>. The preliminary prospectus, dated January 28, 2015, is available on the SEC website. Alternatively, we or the dealer-managers for this offering, Maxim Group LLC and National Securities Corporation, will arrange to send you a preliminary prospectus if you contact Maxim Group LLC, Prospectus Department, 405 Lexington Ave., New York, NY, 10174; Telephone: (212)-895-3745; Email: syndicate@maximgrp.com.

Forward-Looking Statements

All statements in this presentation other than those of historical fact, including statements regarding our preclinical and clinical development plans for Tcelna® and OPX-212, our research and other development programs, our ability to undertake certain activities and accomplish certain goals, projected timelines for our research and development activities and possible regulatory approvals, if any, our expectations regarding the relative benefits of our product candidates versus competitive therapies, our expectations regarding the possibility of licensing or collaborating with third parties regarding our product candidates or research, and our expectations regarding the therapeutic and commercial potential of our product candidates, research, technologies and intellectual property, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “potential” and similar expressions, as well as the negative version of these words and similar expressions, are intended to identify forward-looking statements. Our forward-looking statements do not constitute guarantees of future performance, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those anticipated or implied in such statements. Our forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated as a result of various risks and uncertainties which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and risks inherent in the effort to build a business around such drugs. Although we believe our expectations are reasonable, we do not in any way guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any forward-looking statements. Our forward-looking statements in this presentation speak only as of the date this presentation is actually delivered by us in person. We assume no obligation or undertaking to update or revise any statements to reflect any changes in our expectations or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make that further describe risks and uncertainties relevant to us in additional detail in our filings with the Securities and Exchange Commission, including our registration statement on Form S-1 initially filed on January 28, 2015, as well as in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. You may get these documents for free by visiting EDGAR on the SEC web site at <http://www.sec.gov>.

Opexa Investment Highlights

➤ PIPELINE

- Tcelna[®]: Phase 2b for secondary progressive multiple sclerosis (SPMS), limited competition, \$7BN overall market potential, encouraging prior trials (Phase IIb RRMS, Phase I/II SPMS)
- OPX-212: Pre-IND for neuromyelitis optica (NMO), no approved therapies, orphan indication

➤ TECHNOLOGY

- Precision immunotherapy for T-cell-mediated autoimmune diseases
- Proprietary Platform: potential to yield multiple candidates personalized to each patient
- Company owned and scalable cGMP manufacturing facility
- Strong patent estate (98 domestic and international)

➤ VALIDATION

- Option agreement secured with Merck Serono for Tcelna – strong potential partner
- FDA Fast Track designation for Tcelna in SPMS
- Esteemed Scientific Advisory Board

Offering Summary

Issuer	Opexa Therapeutics, Inc.
Exchange/Ticker	NASDAQ / OPXA
Structure	Rights Offering
Offering size	- Up to 28,776,419 Units - Each Unit composed of one share of common stock and one warrant
Subscription Price	- TBD - Range expected \$0.65-\$0.75
Warrant structure	- Exercise price: \$0.50 per share from issuance through June 30, 2016; \$1.50 per share from July 1, 2016 through 3-year expiration - Redeemable for \$0.01 per share upon certain conditions - Exercisable for cash unless no effective registration statement
Oversubscription privilege	Allocated pro rata up to available Units not purchased by other holders, subject to limitations
Use of proceeds	- Funding of ongoing Phase IIb Abili-T study in SPMS patients - Funding of preclinical and/or clinical development for OPX-212 in NMO - For general corporate purposes and operational purposes
Co-managers	- Maxim Group - National Securities Corp.

Opexa Investment Thesis

➤ Why a Rights Offering?

- A successful rights offering would give Opexa sufficient capital to fund operations through 2016.
 - Complete the ongoing Phase 2b clinical trial in SPMS and release data
 - Potentially initiate a Phase 1/2 trial with OPX-212 in neuromyelitis optica (NMO)

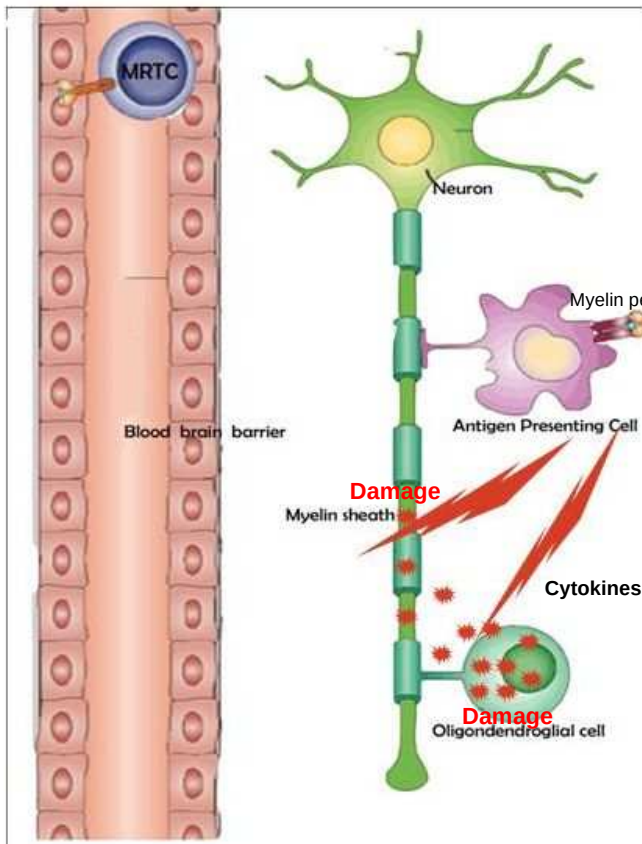
➤ Background

- Opexa has previously raised over \$90 million, with most being invested in its T-cell immunotherapy platform.
- Opexa has conducted two Phase 1 trials and is currently conducting its second Phase 2 trial having treated both RRMS and SPMS patients with Tcelna. Over 400 individuals in total have been enrolled in Opexa's clinical trials for Tcelna, including the ongoing Phase 2b SPMS trial.
- Current Phase 2b trial is designed to show whether Tcelna could improve clinical outcomes - data expected in 2H 2016.
 - Enrollment of 190 patients in a randomized, placebo-controlled trial completed
 - The Company may apply for accelerated approval and breakthrough designation with the FDA following the completion of the current Phase 2b trial in the event of positive results (primary endpoint-wholebrain atrophy; secondary-progression)
- Fast Track Designation obtained from the U.S. FDA for Tcelna in SPMS.
- In addition, the Company has further leveraged its platform to move into neuromyelitis optica (NMO), an orphan (rare) disease with no FDA-approved treatments. This program is in the pre-IND stage.
- Immunotherapy approaches have been validated and are increasingly being applied in oncology.
- Opexa has been refining its approach for over a decade focusing on autoimmune diseases, specifically, Tcelna for MS.
- Based, in part, on data generated in prior MS trials, Merck Serono, a leading pharma company in MS, entered into an option and license agreement with Opexa to potentially license Tcelna for MS, worldwide, excluding Japan. Should Merck Serono exercise its option, they would fund any future Phase III studies and commercial activities with potential milestone payments and royalties coming to Opexa upon success of the program.



HOW DOES TCELNA WORK?

The Root Cause of Multiple Sclerosis

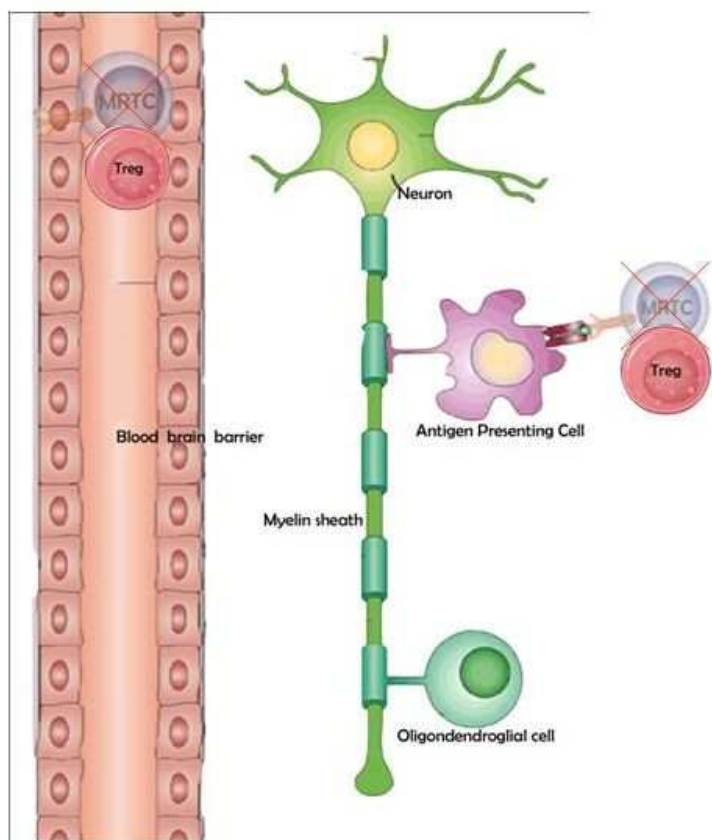


Activated T- cells degrade Myelin and Damage Myelin Producing Cells

- MS is an inflammatory disease in which the insulating cover of the nerve fibers (the myelin sheath) in the brain are damaged by the body's own immune system. There is no cure for MS.
- In MS patients, the faulty immune system is unable to prevent the attack of myelin reactive T-cells (MRTC)
- MRTC cross the blood brain barrier, enter the brain leading to a two pronged attack through:
 1. Destruction of myelin sheath, the protective coating of nerve fibers
 2. Destruction of oligodendroglial cells, which are responsible for producing myelin

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Tcelna Could Address the Root Cause of Multiple Sclerosis by Preventing Demyelination and Enabling Remyelination



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- Immune cells, including Tregs, have been primed, or sensitized to specifically target the pathogenic MRTC for elimination or regulation
- Elimination of harmful MRTC may lead to:
 - o Stabilization of disease by preventing further destruction of myelin
 - o Improvement in condition by allowing Oligodendroglial cells to remyelinate axons (neuroprotection)

Opexa's Strategy

Tcelna programs the immune system to ***specifically*** recognize only the damaging T-cells (MRTC), thereby inhibiting further destruction of the myelin sheath and potentially enabling remyelination



RESULTS AND EXPLANATION OF RRMS & SPMS CLINICAL TRIALS

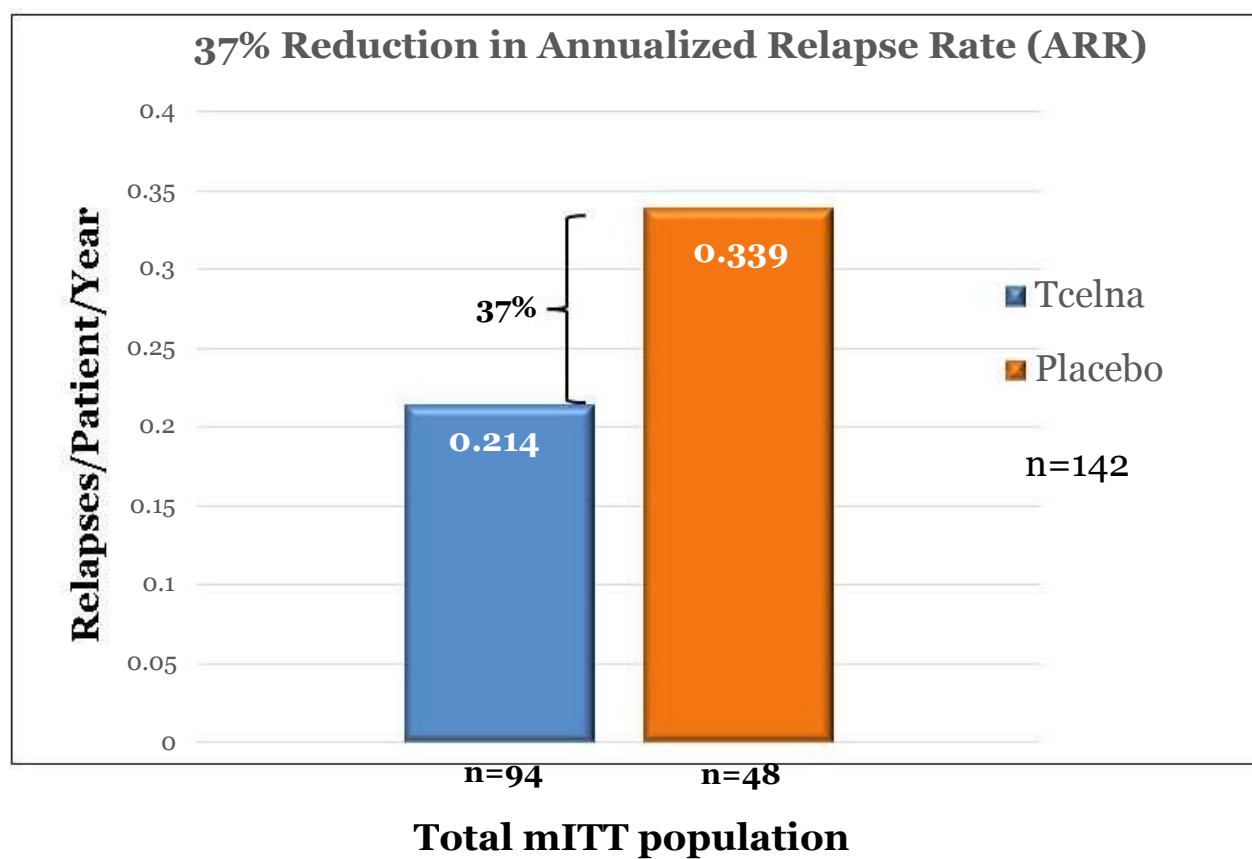
Business Strategy and Rationale for Pursuing Secondary Progressive MS (SPMS)

- **Opexa completed a Phase 2b clinical study in RRMS patients**
 - Although the primary MRI endpoint was not met, the clinical signal was encouraging
 - In a subset of more active RRMS subjects, patients treated with Tcelna saw a statistically significant improvement in disability, and the therapy was safe and well tolerated
 - Opexa completed formal *End of Phase 2* meetings with the FDA and obtained support to move into Phase 3 studies in RRMS
- **In separate Phase I/II trials in SPMS patients, 35 subjects treated with Tcelna showed encouraging results**
 - 80% of patients showed no disease progression following two years of treatment
 - Substantial reduction in relapse rate following two years of treatment
 - One relapse observed in 21 years of cumulative patient follow up
 - No worsening in physical or psychological condition following two years of treatment
 - Well tolerated, no Serious Adverse Events
- **Strong interest from Key Opinion Leaders, clinical investigators, patients and potential partners to advance in SPMS**
- **Substantial unmet medical need in SPMS**
 - Only one product currently approved for SPMS indication with limited use due to cardio toxicity
- **Novel, personalized T-cell approach differentiates Opexa from competition**

Phase 2b RRMS prior clinical trial

Tcelna showed 37% improvement over placebo (mITT)

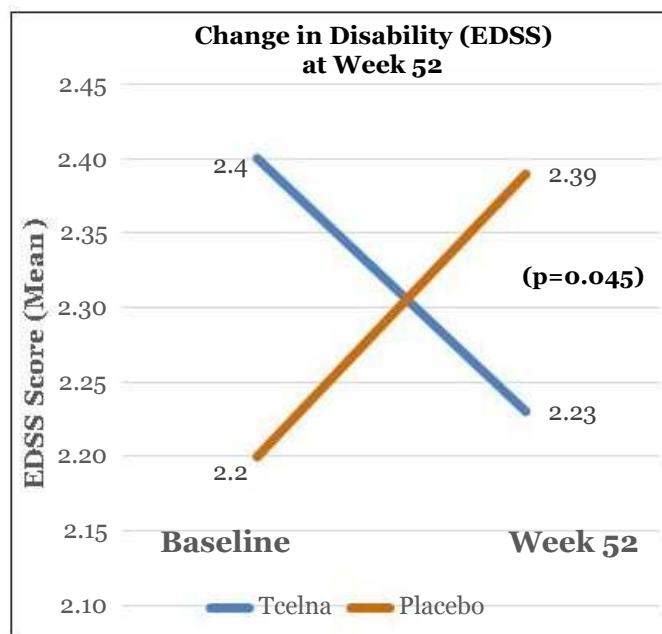
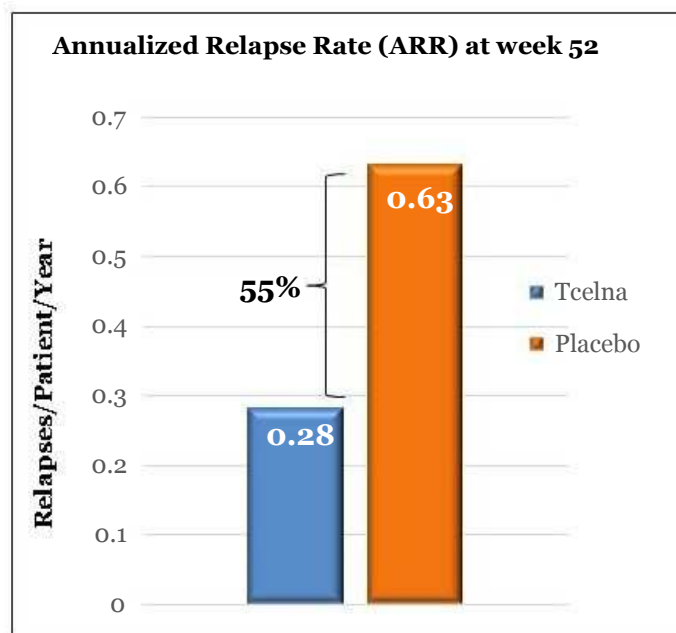
(secondary endpoint measurement, primary MRI endpoint measure not met)



Phase 2b RRMS Prior Clinical Trial

Reversal of Disability in Prospective Analysis in More Active Patients

Sub-population of patients (n=50) with more progressed/active disease profile (baseline ARR >1)

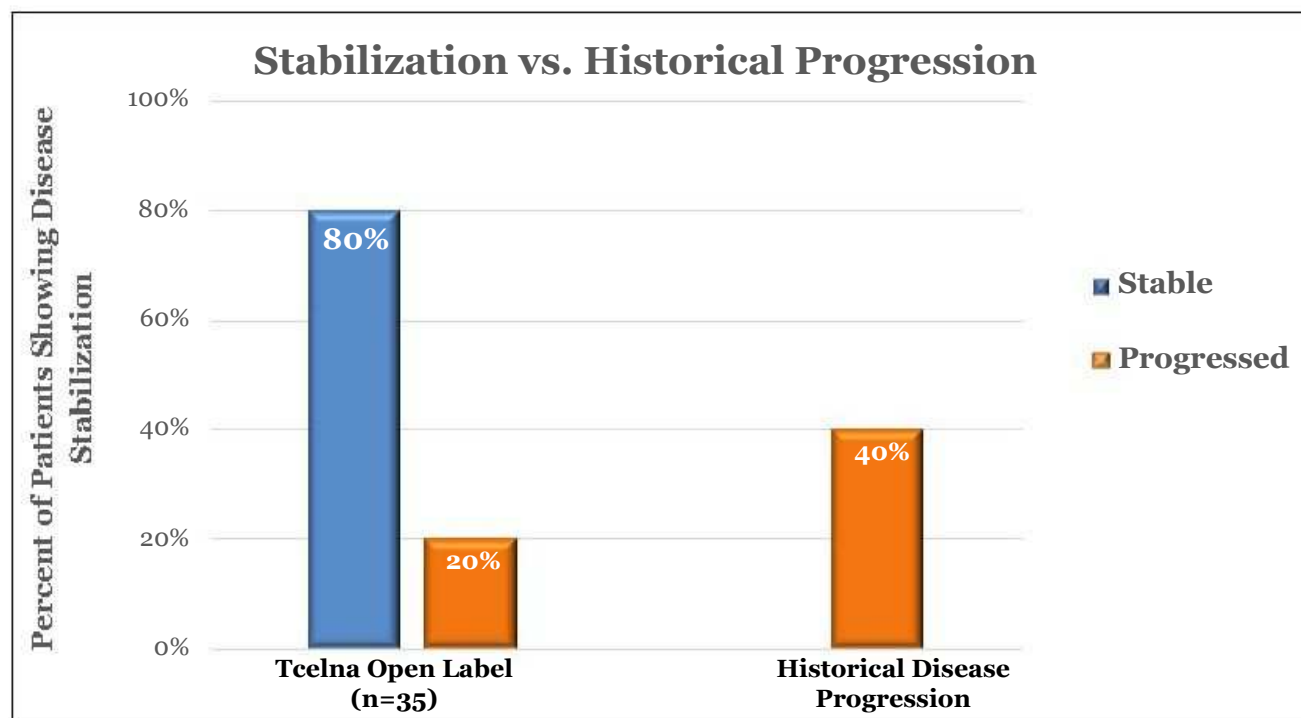


Statistically Significant Improvement in Disability (p=0.045)

Phase I/II SPMS Prior Clinical Trials

Tcelna Stabilizes Disease in SPMS at 2 Years

80% of patients showed no further disease progression by EDSS at 2 years

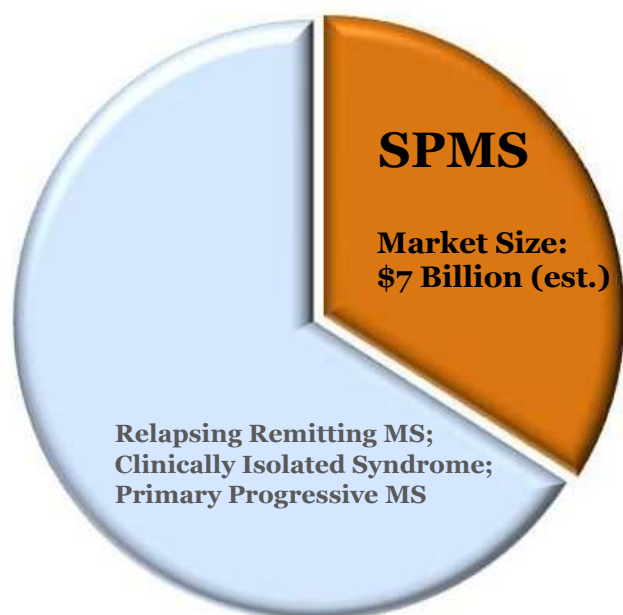


*A small percentage of patients in pooled analysis showed an improvement (i.e. decrease in progression)

**Historical control: ESIMS Study, published *Hommes Lancet* 2004

Tcelna in Secondary Progressive MS

**450,000 Individuals in North America diagnosed with MS;
30-45 % potentially have an SPMS diagnosis**



- Secondary Progressive MS market potential in North America could exceed **\$7 billion** (for all therapies)
- Roughly 150,000 SPMS patients in North America
- Only one drug approved for SPMS in U.S. (none in EU or Asia)
 - Drug not suitable for chronic use due to severe side effects

Tcelna being developed to be a potential therapy of choice in SPMS

Tcelna

Lead Program Targeting Secondary Progressive MS patients

Fast Track Designation by FDA

- **Phase 2b trial is fully enrolled: 190 patients with SPMS**
- **Top line data expected in 2H 2016**
- **Design**
 - Double-blind, 1:1 randomized, placebo-controlled
 - 35 clinical sites in USA and Canada
 - Two annual courses of personalized therapy
 - Efficacy Endpoints: Primary-Whole Brain Atrophy, Secondary-Disease Progression
- **Immune Monitoring being conducted in parallel**
 - Comprehensive biomarker analysis

Merck Serono Agreement

Agreement signed 2013; strong potential partner

Option and License Agreement for worldwide rights to all Multiple Sclerosis indications, excluding Japan

- **If Merck Serono exercises option:**
 - Merck Serono to fund any Phase 3, pre-commercial and commercial activities
 - Merck Serono obtains rights to develop Tcelna for all MS indications
 - Worldwide rights excluding Japan
- **Opexa received \$5 million upfront option fee at signing**
- **Opexa has potential to receive additional \$220 million in option exercise and payments**
- **Opexa has potential to receive royalties ranging from 8% to 15% of annual net sales, with step-ups occurring if net sales exceed \$500 million, \$1 B & \$2 B**
- **Opexa maintains key rights**
 - Development and commercialization rights to Tcelna in Japan
 - Certain manufacturing rights
 - Co-development funding option in exchange for increased royalties
 - Rights to all other disease indications



OPX-212: NEUROMYELITIS OPTICA (NMO)

NMO: A Rare Disease with High Unmet Need and Significant Market Potential

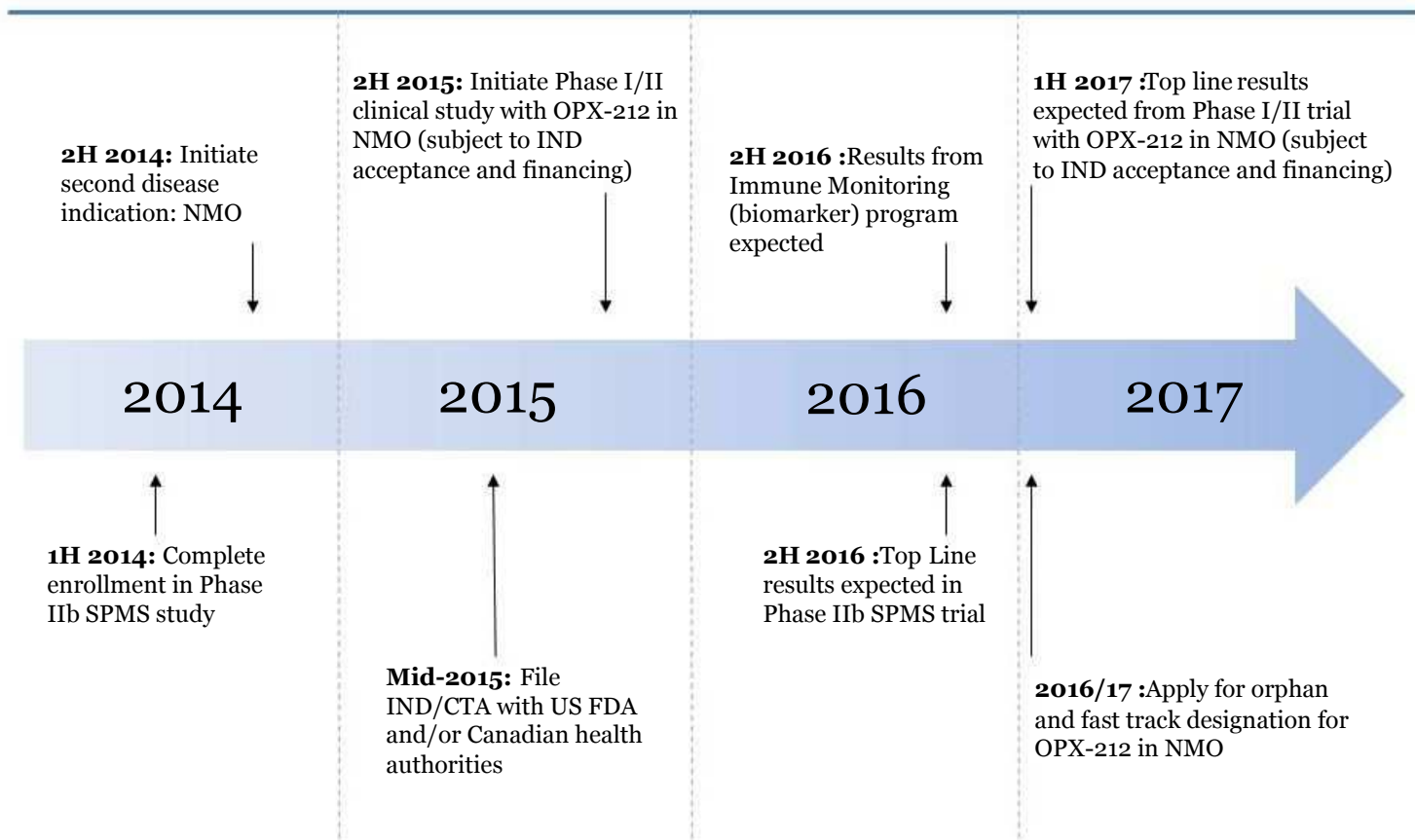


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- Neuromyelitis optica (NMO) is a rare or orphan autoimmune disease, affecting the optic nerves and the spinal cord
- There are no FDA-approved therapies for NMO
- Any therapy that could achieve tolerization of the AQP-4 reactive T-cells may offer a cure for NMO
- Opexa retains world wide rights to OPX-212. Product has potential to generate \$300-\$500 million in peak sales, subject to successful clinical development
- IND filing expected in Mid 2015
- Open label Phase I/II clinical trials expected to start in 2H 2015 (subject to IND acceptance and financing)

An orphan disease with no FDA-approved therapy

Recent and Upcoming Expected Milestones



Experienced Management Team and Board of Directors

Neil Warma, President & CEO, Director

- › 19+ years international healthcare experience with large Pharma and emerging biotechnology companies
- › Former Senior Management, Novartis Pharmaceuticals, Basel, Switzerland
- › Former CEO, Viron Therapeutics, Inc.
- › Co-founder and President of MedExact Inc., a company subsequently acquired

Karthik Radhakrishnan, Chief Financial Officer

- › 10+ years of health care capital markets experience
- › Formerly, Vice President at ING Investment Management
- › MBA, MS in Engineering, CFA charter holder

Don Healey, Ph.D., Chief Scientific Officer

- › 25+ years of experience in cellular immunology and immune regulation
- › Former Director of Immunology, Argos Therapeutics

Donna Rill, Chief Development Officer

- › 30 years in cell and gene therapy research and clinical application
- › Designed and validated cGMP Cell & Gene Therapy Laboratories, Vector Production facilities, and Translational Research Labs

Kenny Frazier, VP of Clinical Dev. and Regulatory Affairs

- › 25+ years of extensive clinical and regulatory experience
- › Formerly, Head of Clinical Operations, Lexicon Pharmaceuticals and Tanox, Inc.

Board of Directors

Timothy Barabe

Board member of Arqule, Inc.; Former CFO of Affymetrix, Human Genome Sciences, Inc., Regent Medical UK and Sandoz GmbH

Dr. Hans-Peter Hartung

Chair of Neurology at Heinrich-Heine University, Germany; Executive Board member of ECTRIMS

Gail J. Maderis

CEO, BayBio, Former CEO of Five Prime Therapeutics, Founder of Genzyme Molecular Oncology

Michael S. Richman

CEO, Amplimmune

Scott B. Seaman

Executive Director, Alkek Foundation

Neil K. Warma

President & CEO, Opexa

SPMS Scientific Advisory Board

- **Dawn McGuire, M.D., FAAN (Chair)**
 - Advisory Council of the Gill Heart Institute
 - Former Vice President of Clinical Research at Elan Pharmaceuticals
- **Hans-Peter Hartung, M.D**
 - Chair of Neurology at Heinrich-Heine University, Düsseldorf
 - Executive Board member ofECTRIMS, World Health Organization Advisory Board on MS
- **Mark S. Freedman, M.D.**
 - Director of the Multiple Sclerosis Research Unit at Ottawa Hospital
 - Multiple Sclerosis Society of Canada, National MS Society (USA)
 - ACTRIMS committee member
- **Clyde Markowitz, M.D.**
 - Director of MS Center at the University of Pennsylvania
- **Doug Arnold, M.D.**
 - James McGill Professor Neurology and Neurosurgery at the Montreal Neurological Institute
- **Edward Fox, M.D., Ph.D.**
 - Director of Multiple Sclerosis Clinic of Central Texas
 - Advisory Committee, Lone Star Chapter of the National Multiple Sclerosis Society



APPENDIX



IMMPATH[®]: PROPRIETARY DRUG DEVELOPMENT PLATFORM

Personalized *T - cell vaccines*

Consisting of Attenuated Antigen Specific T-cell Clones

Personalized T-cell Vaccine

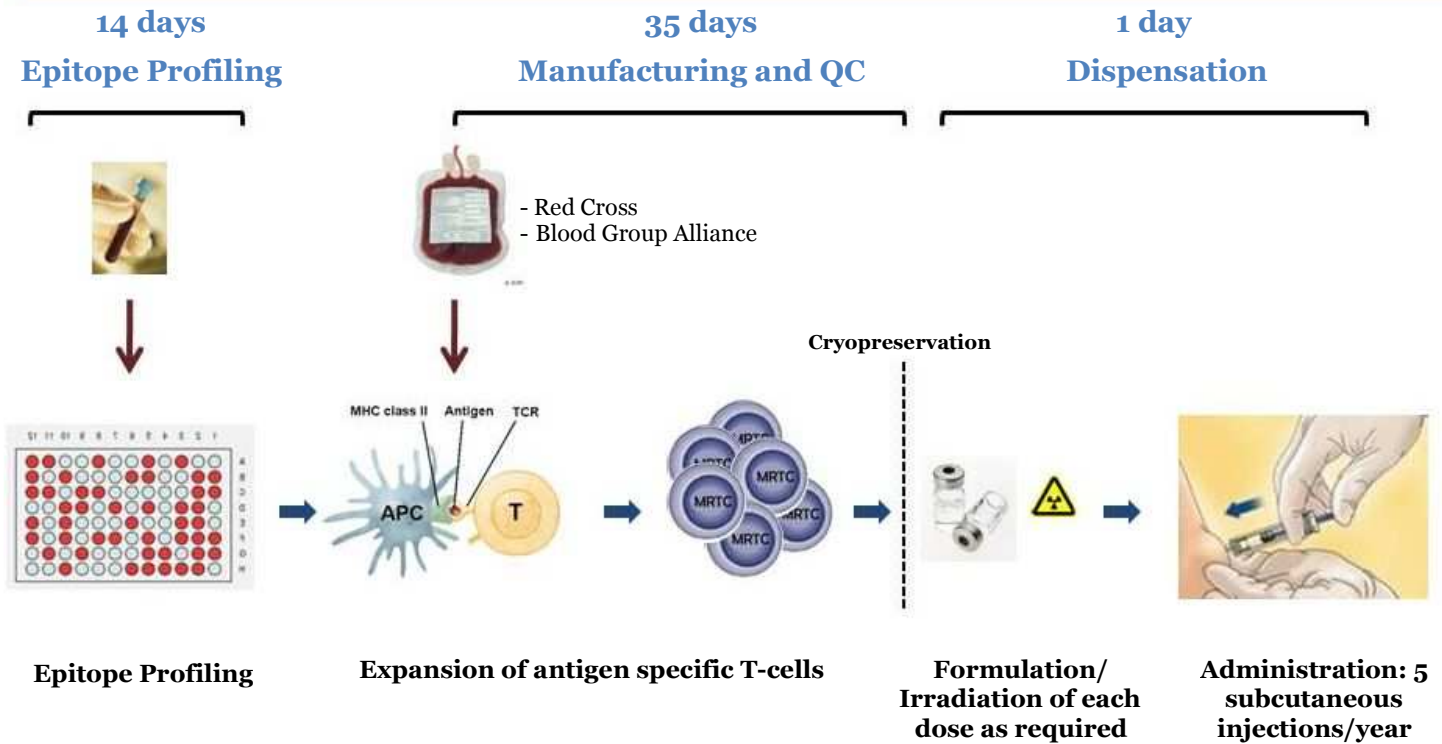


Tcelna: lead product candidate in Phase 2b trial for secondary-progressive multiple sclerosis

- Opexa identifies the exact T-cell responsible for T-cell-mediated autoimmune damage, expands the T-cells in cGMP facility
- Therapeutic dose of attenuated T-cell clones is injected subcutaneously
- Immune system recognizes the large volume of cells (30-45 million) under the skin as potential foreign pathogens
- Attenuated T-cells believed to trigger an immune response specifically targeting circulating pathogenic reactive T-cells

Business Differentiator: Manufacturing Process

Designed for commercialization, Owned and managed by Opexa



Annual course of treatment is 5 doses manufactured from a single procurement

Comprehensive Process to Determine Optimal Additional Indications Beyond Secondary-Progressive MS

