

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (date of earliest event reported): November 10, 2015

OPEXA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Texas

(State or other jurisdiction of
incorporation)

001-33004

(Commission File Number)

76-0333165

(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas

(Address of principal executive offices)

77381

(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On November 10, 2015, Opexa Therapeutics, Inc. (the “Company”) filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and announced its results of operations in a press release.

A copy of the press release announcing the results is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

The Company will host an Analyst and Investor Event on November 10, 2015 where members of the Company’s senior management team will provide an R&D update and review of the Company’s Abili-T clinical trial for Secondary Progressive Multiple Sclerosis and the development program for Neuromyelitis Optica (NMO).

The Analyst and Investor Event will take place at the New York Hilton Midtown. A live webcast of the event will start at 5:15 p.m. Eastern Time and may be accessed on the Investor Relations section of the Company’s website, www.opexatherapeutics.com. The event should conclude by 7:00 p.m. An archived version of the webcast will be available for 90 days after the event on the Company’s website.

A copy of the slides that will be presented at the Analyst and Investor Event are furnished as Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference. The Company does not undertake to update this slide presentation.

Item 8.01. Other Events.

On November 10, 2015, the Company issued a press release announcing supportive results of an animal study completed as part of its preclinical development activities to support OPX-212, the Company’s personalized T-cell immunotherapy in development for the treatment of NMO. The study results show that T-cell immunotherapy with attenuated antigen-specific T-cells suppress the T-cell response to Aquaporin-4 (AQP4) in a dose-dependent manner, compared to vehicle control, as measured by reduction in both Aquaporin-4 reactive T-cell (ARTC) proliferation and associated cytokine activity. The results were statistically significant.

In NMO, ARTC mount an attack against Aquaporin-4, the autoantigen in NMO, leading to secondary demyelination of nerve fibers within the optic nerves and the spinal cord, resulting in the clinical symptoms of the disease. The Company’s therapeutic approach is to suppress or reduce the number of these activated ARTC in patients with NMO. The results of the preclinical animal study provide evidence that T-cell immunotherapy reduces the level of activated ARTC in a murine (mouse) model.

A copy of the press release announcing the study results is attached as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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<u>99.1</u>	Press release issued by Opexa Therapeutics, Inc. on November 10, 2015 regarding quarterly earnings.
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<u>99.2</u>	Opexa Therapeutics, Inc. slide presentation for Analyst and Investor Event on November 10, 2015.
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<u>99.3</u>	Press release issued by Opexa Therapeutics, Inc. on November 10, 2015 regarding preclinical study results.
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The information in Item 2.02 and 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 10, 2015

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

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Opexa Therapeutics Reports Third Quarter 2015 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas (November 10, 2015) - Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders including multiple sclerosis (MS) and neuromyelitis optica (NMO), today reported financial results for the three months ended September 30, 2015 and provided an update on the Company's recent corporate developments.

Recent highlights include:

Clinical and Operational Highlights

- The Phase 2b clinical trial of Tcelna[®] (*imilecleucel-T*) in secondary progressive multiple sclerosis (SPMS) (Abili-T trial) continued to advance in the third quarter. Top line data is expected in the second half of 2016. The two-year trial is fully enrolled and to date, approximately 92% of the total patient visits have been completed. The Abili-T clinical trial is a randomized, double-blind, placebo-controlled study being conducted at approximately 35 leading clinical sites in the U.S. and Canada.
 - A preclinical bioactivity animal study conducted for Opexa's neuromyelitis optica (NMO) development program showed evidence that T-cell immunotherapy with attenuated antigen-specific T-cells significantly suppressed the T-cell response to Aquaporin-4 (AQP4) in a dose-dependent manner, compared to vehicle control, as measured by reduction in both Aquaporin-4 reactive T-cells (ARTC) proliferation and associated cytokine activity. The results were statistically significant.
 - Opexa expanded its intellectual property portfolio with the issuance of four additional key patents covering its broad T-cell immunotherapy platform. The recent allowances bring the number of granted U.S. and international patents in Opexa's patent portfolio to 160, including in-licensed patents. The expansion of Opexa's intellectual property portfolio further strengthens the patent estate surrounding Tcelna, Opexa's personalized T-cell immunotherapy in development for the treatment of secondary progressive multiple sclerosis.
 - At a recent and regularly scheduled meeting, the independent Data and Safety Monitoring Board (DSMB) overseeing Opexa's Abili-T trial recommended the trial continue as planned based on the committee's review of safety data from the trial. Opexa has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for Tcelna in SPMS.
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- During the third quarter of 2015, Opexa continued with IND-enabling activities to support OPX-212, Opexa's preclinical development candidate for NMO. The Company expects to submit an IND and be in a position to initiate a Phase 1/2 proof-of-concept clinical trial in the first half of 2016, assuming the availability of sufficient resources.

Financial Highlights

- In September 2015, Opexa entered into a stock purchase agreement with investors to fund the Company's NMO program, including its planned Phase 1/2 trial, pursuant to which Opexa sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of \$4.40 and issued warrants to purchase a like number of shares, for a total purchase price of \$499,999. Opexa also agreed to sell and the purchasers agreed to purchase an additional aggregate of \$4.5 million of common stock in four additional tranches upon achievement of certain pre-specified milestones to further the clinical development of OPX-212. Each subsequent tranche will include the sale of common stock only (i.e., no additional warrants will be issued), with such shares priced at 90% of the 10-day volume weighted average price of Opexa's common stock immediately preceding the occurrence of the related milestone.
- Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity to support its current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities into the fourth quarter of 2016. Opexa expects top-line data for the Abili-T trial to be available in the second half of 2016, and thus believes it has sufficient resources to complete such trial.

"The third quarter of 2015 progressed well with the focus remaining clearly on the conduct of the Phase 2b Abili-T clinical study in secondary progressive multiple sclerosis," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "The trial continues to move toward completion as we expect top-line results in the second half of next year. With no treatments approved for patients with the progressive form of MS, we remain committed in our efforts to advance what, we believe, could be the first safe and effective treatment for this patient population."

"We are also pleased with the results of the bioactivity animal study we have been running over the past several months, which support our development candidate, OPX-212, in neuromyelitis optica. The results are encouraging and show a dose-dependent reduction in Aquaporin-4 reactive T-cells in the mouse model utilized. We believe this adds support to our hypothesis around the mechanism of action for our therapy and we expect to include the data as part of our IND submission for OPX-212 in NMO. We are continuing with the preclinical development activities of OPX-212, including completing the manufacturing runs and expect to submit the IND to the U.S. FDA and be in a position to open a Phase 1/2 clinical study in NMO patients in the first half of 2016, assuming the availability of sufficient resources. The private financing that was secured in the third quarter of 2015 is in support of the NMO program and could provide Opexa with up to \$5 million in tranching funding for the Phase 1/2 clinical trial, subject to hitting pre-determined milestones," added Mr. Warma.

Third Quarter Financial Results

Opexa reported revenue of \$726,291 and \$307,686 for the three months ended September 30, 2015 and 2014, respectively. The revenue is related to the recognized portion of the \$5 million upfront payment received from Merck Serono in conjunction with the Option and License Agreement entered into between Opexa and Merck Serono during February 2013 and the \$3 million payment from Merck Serono in connection with the March 2015 amendment.

Research and development expenses were \$2,420,220 for the three months ended September 30, 2015, compared with \$3,173,538 for the three months ended September 30, 2014. The decrease in expenses is primarily due to a decrease in the procurement and use of supplies for product manufacturing and development, a decrease in the investigator costs associated with the ongoing clinical trial of Tcelna in SPMS and lower intellectual property legal fees.

General and administrative expenses for the three months ended September 30, 2015 were \$1,023,848, compared with \$917,335 for the three months ended September 30, 2014. The increase in expense is primarily due to an increase in legal costs and employee compensation and was partially offset by lower consultant expenses.

Depreciation and amortization expenses for the three months ended September 30, 2015 were \$89,018, compared with \$97,364 for the three months ended September 30, 2014. The decrease in expense is due to some assets being fully amortized and was partially offset by increases in depreciation for laboratory, manufacturing and computer equipment acquired during 2014 and 2015.

Interest income net of interest expense was \$2,222 for the three months ended September 30, 2015, compared to \$2,498 for the three months ended September 30, 2014.

Other income was \$11,760 for the three months ended September 30, 2015, compared to \$0 in the three months ending September 30, 2014. This was primarily driven by a gain on exchange rate, which was related to two clinical sites located in Canada and the difference between the Canadian dollar and the US dollar on payments to these clinical sites. Payments to these sites began in December 2014.

Net loss reported for the three months ended September 30, 2015 was approximately \$2.8 million, or \$0.42 loss per share (basic and diluted), compared with a net loss of approximately \$3.9 million, or \$1.11 loss per share (basic and diluted), for the three months ended September 30, 2014. The decreased net loss for the quarter is primarily related to the increase in revenue due to the March 2015 amendment to our Option and License Agreement with Merck Serono and a decrease in research and development expenses, which was partially offset by the increase in general and administrative expenses.

Cash and cash equivalents were \$15,592,500 as of September 30, 2015, compared to \$9,906,373 as of December 31, 2014.

For additional information please see Opexa's Quarterly Report on Form 10-Q filed today with the SEC.

Opexa Therapeutics to Webcast Analyst and Investor Event

Opexa will host an Analyst and Investor Event today where members of Opexa's senior management team will provide an R&D update and review of the Company's Abili-T clinical trial for Secondary Progressive Multiple Sclerosis and the development program for Neuromyelitis Optica. The Analyst and Investor Event will take place at the New York Hilton Midtown.

A live webcast of the event will start at 5:15 p.m. Eastern Time and may be accessed [here](#), or on the Investor Relations section of the Company's website, www.opexatherapeutics.com. The event should conclude by 7:00 p.m. An archived version of the webcast will be available for 90 days after the event on the Company's website.

About Opexa

Opexa is a biopharmaceutical company developing a personalized immunotherapy with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases such as neuromyelitis optica (NMO). These therapies are based on Opexa's proprietary T-cell technology. The Company's leading therapy candidate, Tcelna®, is a personalized T-cell immunotherapy that is in a Phase IIb clinical development program (the Abili-T trial) for the treatment of secondary progressive MS. Tcelna consists of myelin-reactive T-cells, which are expanded ex vivo from the patient's peripheral blood and reintroduced into the patient in an attenuated form via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin for each individual patient.

For more information, visit the Opexa Therapeutics website at www.opexatherapeutics.com or follow company news on [Twitter](#) via [@OpexaCEO](#).

Cautionary Statement Relating to Forward-Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

Statements contained in this release, other than statements of historical fact, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "expects," "believes," "may," "intends," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that forward-looking statements, including without limitation statements regarding the safety, efficacy and projected development timeline of drug candidates such as Tcelna® and OPX-212 constitute forward-looking statements. These 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 in such forward-looking statements as a result of various risks and uncertainties, which include without limitation our ability to raise additional capital to continue our development programs, our ability to successfully develop potential products such as Tcelna and OPX-212, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and OPX-212), as well as other risks associated with the process of discovering, developing and commercializing drug candidates that are safe and effective for use as human therapeutics. These and other risks are described in detail in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2014 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. All forward-looking statements contained in this release speak only as of the date on which they were first made by us, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after such date.

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Option revenue	\$ 726,291	\$ 307,686	\$ 1,830,036	\$ 964,209
Expenses:				
Research and development	2,420,220	3,173,538	7,853,076	9,393,887
General and administrative	1,023,848	917,335	3,375,602	2,987,582
Loss on disposition of assets	1,167	-	1,167	-
Depreciation and amortization	89,018	97,364	280,003	291,608
Operating loss	(2,807,962)	(3,880,551)	(9,679,812)	(11,708,868)
Interest income, net	2,222	2,498	5,290	11,982
Other income, net	11,760	-	32,781	-
Net loss	<u>\$ (2,793,980)</u>	<u>\$ (3,878,053)</u>	<u>\$ (9,641,741)</u>	<u>\$ (11,696,886)</u>
Basic and diluted loss per share	\$ (0.42)	\$ (1.11)	\$ (1.75)	\$ (3.38)
Weighted average shares outstanding - Basic and diluted	6,709,251	3,478,324	5,498,228	3,461,479

Selected Balance Sheet Data:

	September 30, 2015	December 31, 2014
	(unaudited)	
Cash and cash equivalents	\$ 15,592,500	\$ 9,906,373
Subscription receivable	232,934	-
Other current assets	329,323	758,943
Fixed assets, net	886,878	1,098,104
Other long term assets	9,734	38,939
Total assets	17,051,369	11,802,359
Total current liabilities	4,964,564	3,132,424
Total long-term liabilities	726,293	1,230,748
Total stockholders' equity	11,360,512	7,439,187
Total liabilities and stockholders' equity	\$ 17,051,369	\$ 11,802,359

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Source: Opexa Therapeutics, Inc.

Company Contact:

Karthik Radhakrishnan

Opexa Therapeutics, Inc.

Chief Financial Officer

281-775-0600

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OPEXA THERAPEUTICS



Opexa Therapeutics, Inc.

NASDAQ: OPXA

Analyst & Investor Event

November 10, 2015

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 of this presentation. 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 Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. You may get these documents for free by visiting EDGAR on the SEC web site at <http://www.sec.gov>.

Agenda

- | | |
|--------------|---|
| 5:15-5:20 PM | • Welcome |
| 5:20-5:40 PM | • Opexa Corporate Update <ul style="list-style-type: none">– Neil Warma, CEO & Don Healey, CSO<ul style="list-style-type: none">• Multiple Sclerosis Program• Neuromyelitis Optica (NMO) Preclinical Program• NMO Bioactivity Study Data |
| 5:40-6:00 PM | • Dr. Clyde Markowitz <ul style="list-style-type: none">– MS program & Abili-T Trial for Secondary Progressive MS |
| 6:00-6:20 PM | • Dr. Ben Greenberg <ul style="list-style-type: none">– OPX-212 Development Program for NMO |
| 6:20-7:00 PM | • Q&A |

Clyde Markowitz, M.D.

- Associate Professor of Neurology at the Hospital of The University of Pennsylvania
- Expert in the field of MS involved with many clinical trials developing new compounds for the treatment of MS
- Director of the MS Center at the University of Pennsylvania and Professor of Neurology at the University of Pennsylvania School of Medicine in Philadelphia
- Author of over 35 publications
- Member of the American Academy of Neurology
- Serves as the Chairman of the Clinical Advisory Committee for the Delaware Valley chapter of the National Multiple Sclerosis Society
- Member of Opexa's Scientific Advisory Board
- Clinical Investigator for the Abili-T Trial in SPMS

Benjamin Greenberg, M.D., M.H.S.

- Associate Professor and the Cain Denius Scholar in Mobility Disorders in the Department of Neurology and Neurotherapeutics at UT Southwestern Medical Center
- Internationally recognized expert in treating adults and children with rare autoimmune disorders of the central nervous system
- Specializes in treating patients with transverse myelitis (TM), neuromyelitis optica (NMO), and multiple sclerosis (MS), and other conditions such as autoimmune encephalitis and acute demyelinating encephalomyelitis (ADEM).
- Author of over 45 publications
- Member of the American Board of Psychiatry and Neurology

Opexa Investment Highlights

➤ PIPELINE

- **Tcelna®**: Phase 2b for **secondary progressive multiple sclerosis (SPMS)**, limited competition, \$7BN overall market potential
- **OPX-212**: Pre-IND for **neuromyelitis optica (NMO)**, no approved therapies, **orphan** indication

➤ TECHNOLOGY

- **Personalized T-cell immunotherapy platform** for autoimmune diseases
- Potential to yield multiple candidates tailored to each patient's disease profile
- **Scalable cGMP manufacturing facility**
- Strong patent estate (160 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

Recent and Upcoming Expected Milestones

Tcelna: Multiple Sclerosis

- ✓ Q3 2015: 92% of all patient visits in Abili-T trial have been completed
- ✓ Q3 2015: The independent Data and Safety Monitoring Board (DSMB) overseeing Opexa's Abili-T trial met and recommended the trial continue as planned
- 2H 2016: Top line results expected for Abili-T Phase 2b SPMS trial

OPX-212: Neuromyelitis Optica

- ✓ Q3 2015: Secured \$5 million in funding to support OPX-212 NMO development, including Phase I/II proof-of-concept clinical trial, of which \$4.5M is subject to timely satisfaction of milestones
- ✓ Q3 2015: Results of preclinical animal study showed statistically significant dose dependent reduction of AQP4 reactive T-cells in murine (mouse) model
- 1H 2016: Expect to submit IND and be in a position to initiate Phase I/II proof-of-concept clinical trial, assuming the availability of sufficient resources

Recent and Upcoming Expected Milestones

IP

- ✓ Q3 2015: Four additional key patents issued covering T-cell immunotherapy platform
- ✓ 160 total granted U.S. and international patents in Opexa's patent portfolio, including in-licensed patents

Financial (as of Sept 30, 2015)

- ~\$15.6 million cash
- No Debt
- Historical monthly burn: ~\$1.1 million
- Cash runway into Q4 2016
- Shares outstanding ~6.8 million

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 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 Phase 3, pre-commercial and commercial activities
 - Opexa has potential to receive up to an additional \$220 million in option exercise and milestone 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
- Merck Serono increased their commitment to Opexa's MS program this year
 - In anticipation of the Phase IIb trial results expected in 2H 2016, Merck Serono gave Opexa \$3 million of support in March 2015 to begin planning for Phase III studies



LEVERAGING THE T-CELL PLATFORM: OPX-212 FOR NEUROMYELITIS OPTICA (NMO)



OPX-212: Opexa's Orphan Disease Program

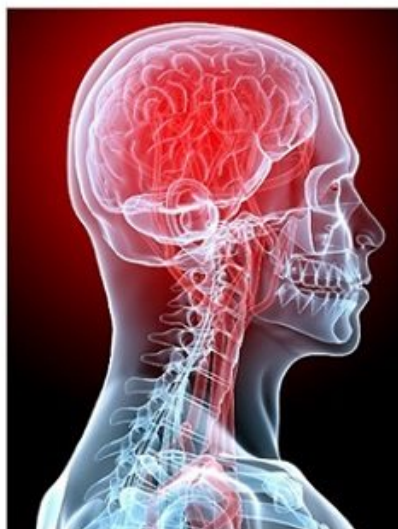


Image reprinted with permission from MultiView, Inc.

- Neuromyelitis optica (NMO) is a rare or orphan autoimmune disease
- Immune system cells and antibodies mistakenly attack and destroy myelin cells in the optic nerves and the spinal cord
- Individuals with NMO develop optic neuritis, which causes pain in the eye and vision loss, and transverse myelitis, which causes weakness, numbness, and sometimes paralysis of the arms and legs
- There are no FDA-approved therapies for NMO
- Affects any age varying from 3 to 90 years, the average age of onset ~41 years

An orphan disease with no FDA-approved therapy



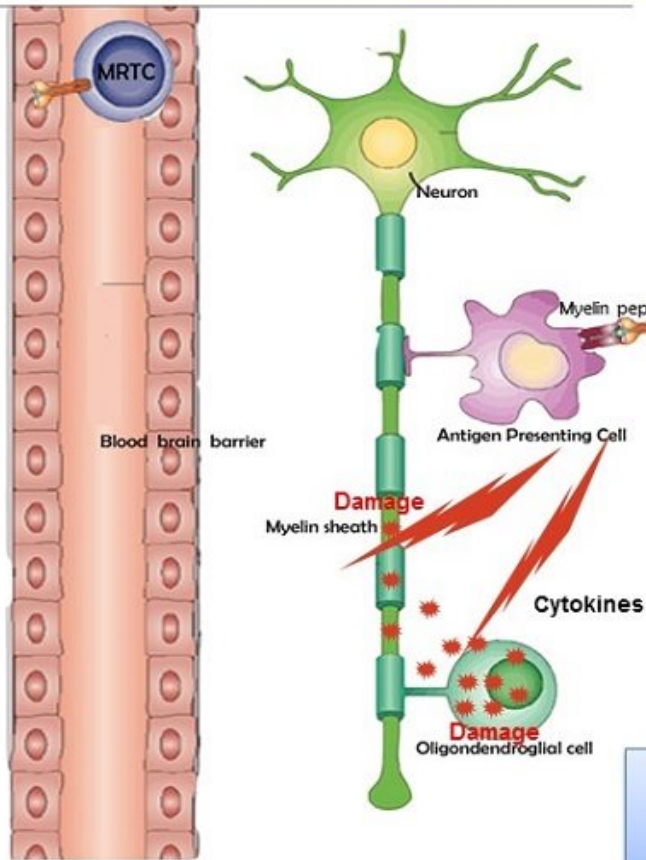
OPEXA THERAPEUTICS

OPEXA'S NOVEL APPROACH; PRIMING THE IMMUNE SYSTEM



Precision Immunotherapy®

Root cause of MS: Activated T-cells degrade myelin and damage myelin producing cells

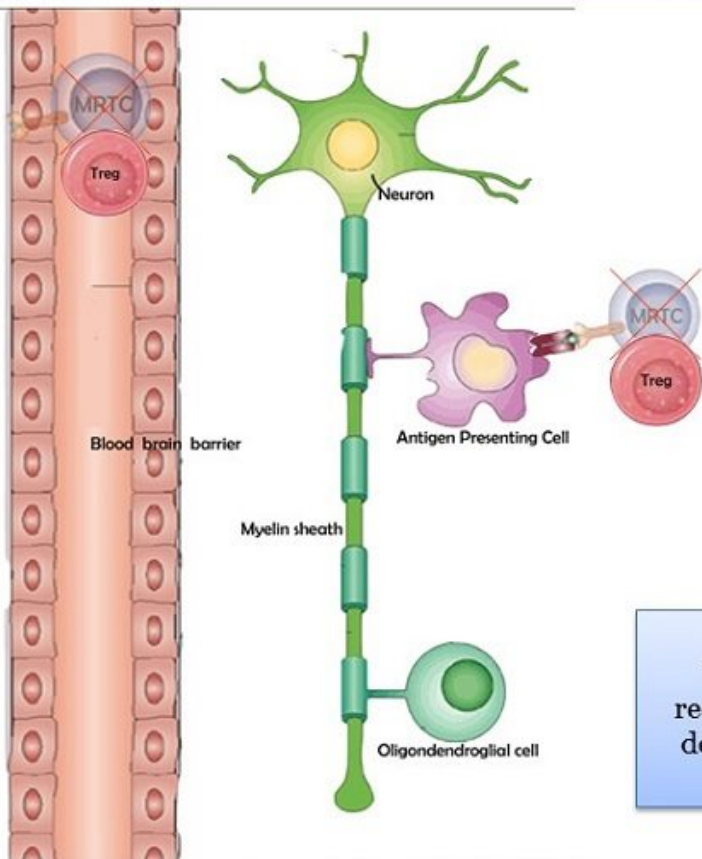


- In MS patients, the faulty immune system is not able to prevent the attack of a small sub-population of myelin reactive T-cells (MRTC)
- MRTCs cross the blood brain barrier, enter the brain, and bind to antigen presenting cells (APC), causing a release of pro-inflammatory cytokines which lead to a 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

Result

Destruction of the myelin sheath and myelin producing cells, thereby preventing remyelination

Tcelna could address the root cause of MS by preventing demyelination and enabling remyelination



- Therapeutic dose of Tcelna (attenuated T-cell clones) is injected subcutaneously
- This triggers an immune response specifically targeting circulating MRTc
- Immune cells, including Tregs, have been primed, or sensitized, we believe, to specifically target the pathogenic MRTc for elimination or regulation
- Elimination of harmful MRTc may lead to:
 1. Stabilization of disease by preventing further destruction of myelin
 2. Improvement in condition by allowing oligodendroglial cells to remyelinate axons (neuroprotection)

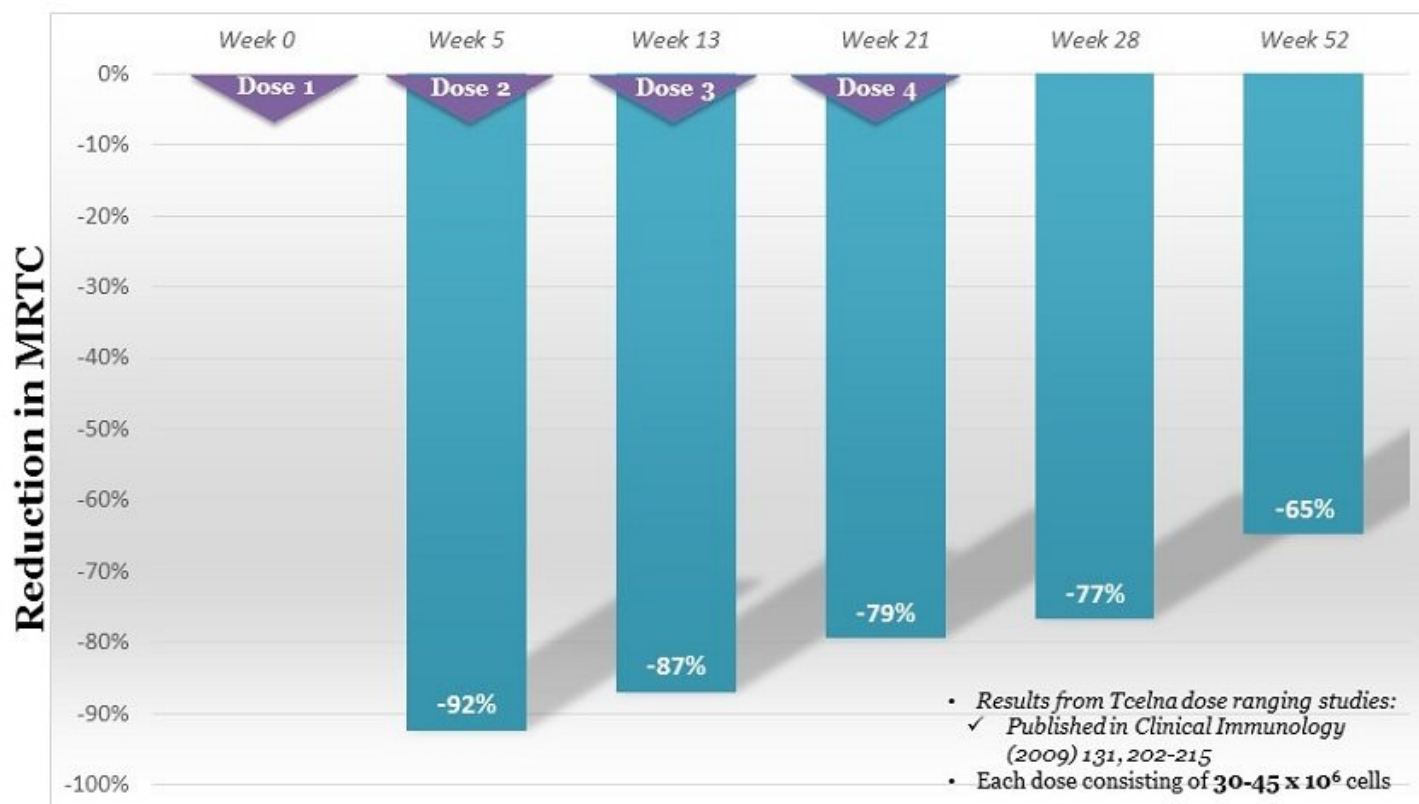
Opexa's Strategy

Tcelna programs the immune system to **specifically** recognize MRTc as pathogenic, thereby inhibiting further destruction of the myelin sheath and potentially enabling remyelination

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Clinical evidence for Tcelna MoA

T-cell technology demonstrated a significant reduction in reactive T-cells (52 week study results of MS)



MRTC: Myelin Reactive T-cells



OPEXA THERAPEUTICS

OPX-212: BIOACTIVITY STUDY



Precision Immunotherapy®

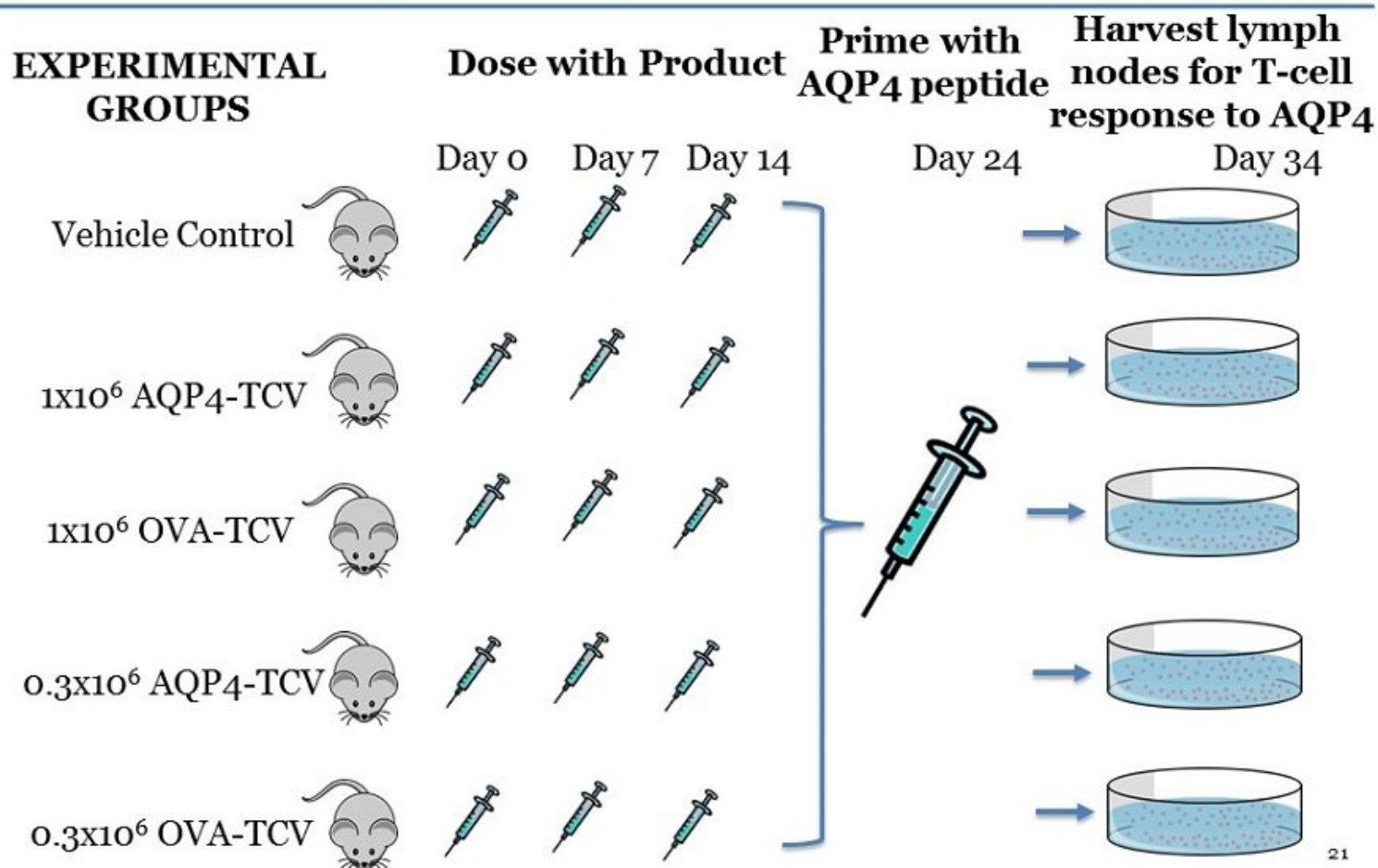
NMO Bioactivity animal study results

- Bioactivity study supports development of OPX-212
- Opexa's T-cell technology suppresses an immune response in mice relevant to the immunopathology of NMO
- Results statistically significant
- Evidence from the bio-activity study, demonstrating the potency of autologous murine T-cell products in mice primed to aquaporin-4, is an important component of our IND submission to FDA

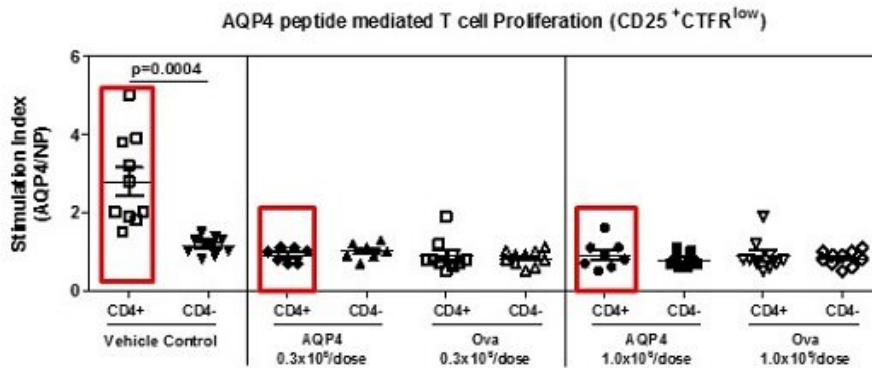
NMO Bioactivity study rationale

- *Hypothesis:* Can immunotherapy with attenuated T-cells reduce a T-cell response to the Neuromyelitis Optica (NMO) associated autoantigen, aquaporin-4?
- No animal model of NMO has been established that exhibits both endogenous T-cell dependent immunity and autoantibody production to aquaporin-4
- Opexa developed a model whereby mice would be pre-treated with attenuated antigen-specific T-cells, leading to the suppression of a T-cell response to aquaporin-4, when animals were primed with the NMO autoantigen in adjuvant
- The model would be utilized to show a dose-dependent effect of T-cell immunotherapy on immunity to aquaporin-4

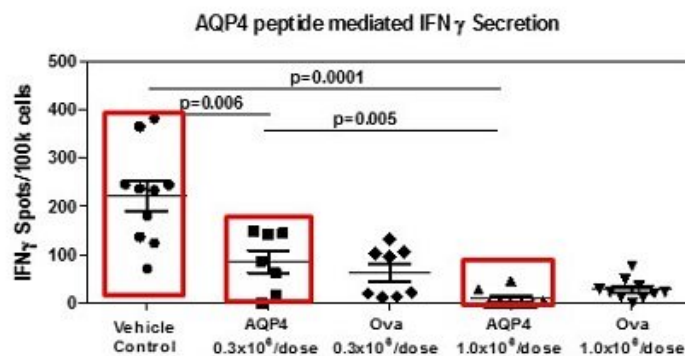
Bioactivity Study Protocol



Results: Suppression of a T-cell response to Aquaporin-4



- Pre-treatment of B6 mice with attenuated T-cells suppresses priming to AQP4 antigen in a dose dependent manner





OPEXA THERAPEUTICS

Clyde Markowitz, M.D.

Associate Professor of Neurology at the Hospital of The
University of Pennsylvania





OPEXA THERAPEUTICS

ABILI-T TRIAL: SPMS DESIGN



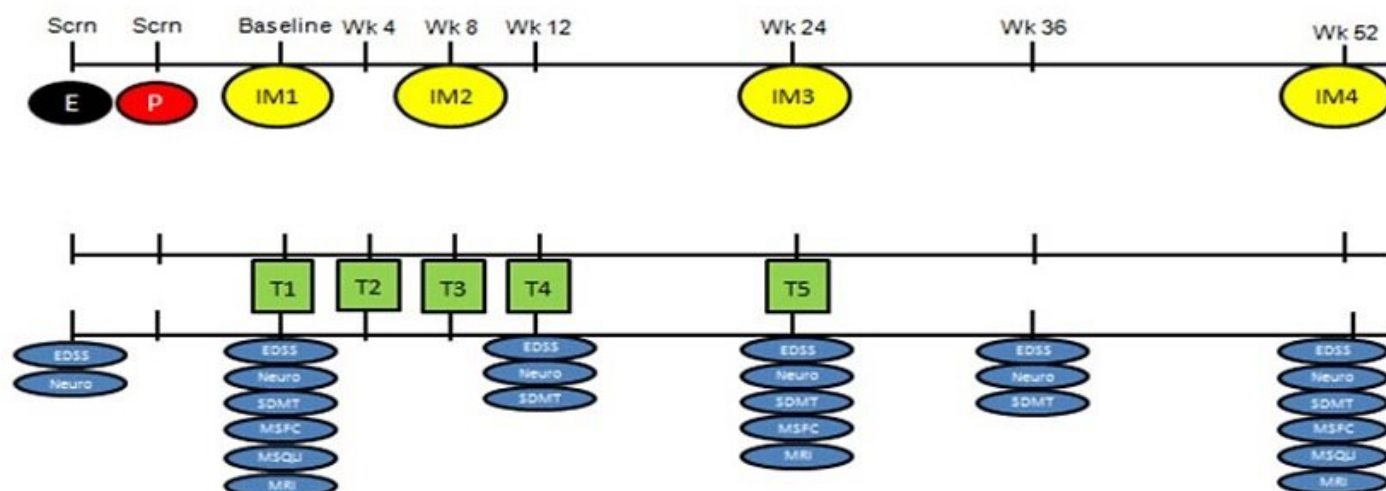
Precision Immunotherapy®

Abili-T Trial: SPMS Design

Fast Track designation granted by FDA

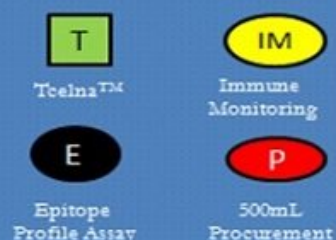
- **Abili-T Phase IIb clinical trial is ongoing**
 - Double-blind, 1:1 randomization, placebo-controlled
 - Subjects with Secondary Progressive MS
 - EDSS of 3.0 to 6.0
 - Immune Monitoring program
- **190 Subjects enrolled**
 - 35 sites in USA and Canada
- **2 annual courses of personalized therapy**
 - Baseline, Week 4, 8, 12, 25

Two Year Dosing Regimen



Efficacy Assessments

EDSS: Expanded Disability Status Scale
 NEURO: Neurological Examination
 SDMT: Symbol Digit Modalities Test
 MSFC: MS Functional Composite
 MSQI: MS Quality of Life Indicator
 MRI: Magnetic Resonance Imaging



2 - 1 mL injections given SubQ



OUTCOME MEASURES



Efficacy Assessments

Primary Endpoint:

- Percent of whole-brain atrophy
 - ❖ Brain atrophy is a clinically relevant and robust component of disease progression in MS
 - Measurement of axonal loss; rate of axonal loss is $\sim 0.5\%/yr$
 - ❖ Progressive whole-brain atrophy can be detected in vivo in a sensitive and reproducible manner by MRI
 - ❖ Data linking atrophy to clinical disability and determinant of disease progression
 - ❖ ABILI-T is 80% powered to show a 37.5% relative difference in atrophy over two years
 - ❖ n of 180 optimized likelihood of obtaining a statistically significant outcome

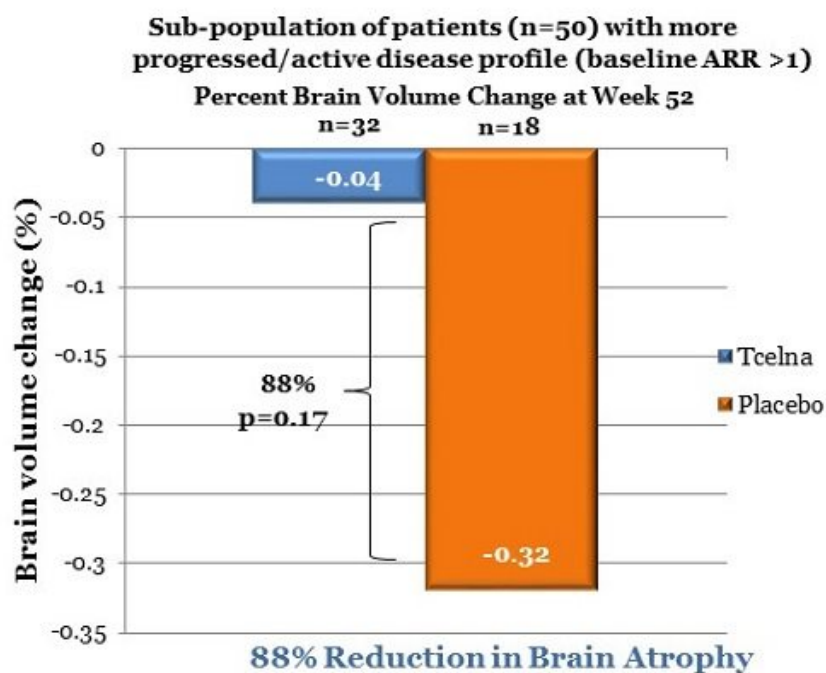
Efficacy Assessments (cont.)

Key Secondary Endpoints:

- Sustained progression measured by EDSS
- Composite endpoint that includes
 - EDSS increase sustained for 12 weeks, or
 - A 20% increase in time, sustained for 24 weeks, in one of the following changes in disability:
 - » Timed 25 Foot Walk (T25FW) and/or
 - » 9 Hole Peg Test (9HPT)
- ❖ In line with Phase 3 endpoint accepted by FDA

Supportive Brain Atrophy Data for ARR>1 from TERMS study

- TERMS was a Phase IIb study of Tcelna in relapsing remitting MS patients completed in 2008
- Although TERMS did not show statistical significance in its primary endpoint (cumulative number of GdE lesions determined by MRI), it did show compelling evidence of efficacy in various clinical and other MRI endpoints
- p-value for ARR >1 from TERMS is 0.17 over the 1-year study
- The statin study (Chataway *et al* Lancet June 2014) showed that one can successfully design a 150 patient study to show benefit on brain atrophy
- Abili-T trial is a 1:1 randomized two-year study and we believe that we can show a benefit on atrophy over the two year duration





OPEXA THERAPEUTICS

PREVIOUS OPEXA SPMS DATA

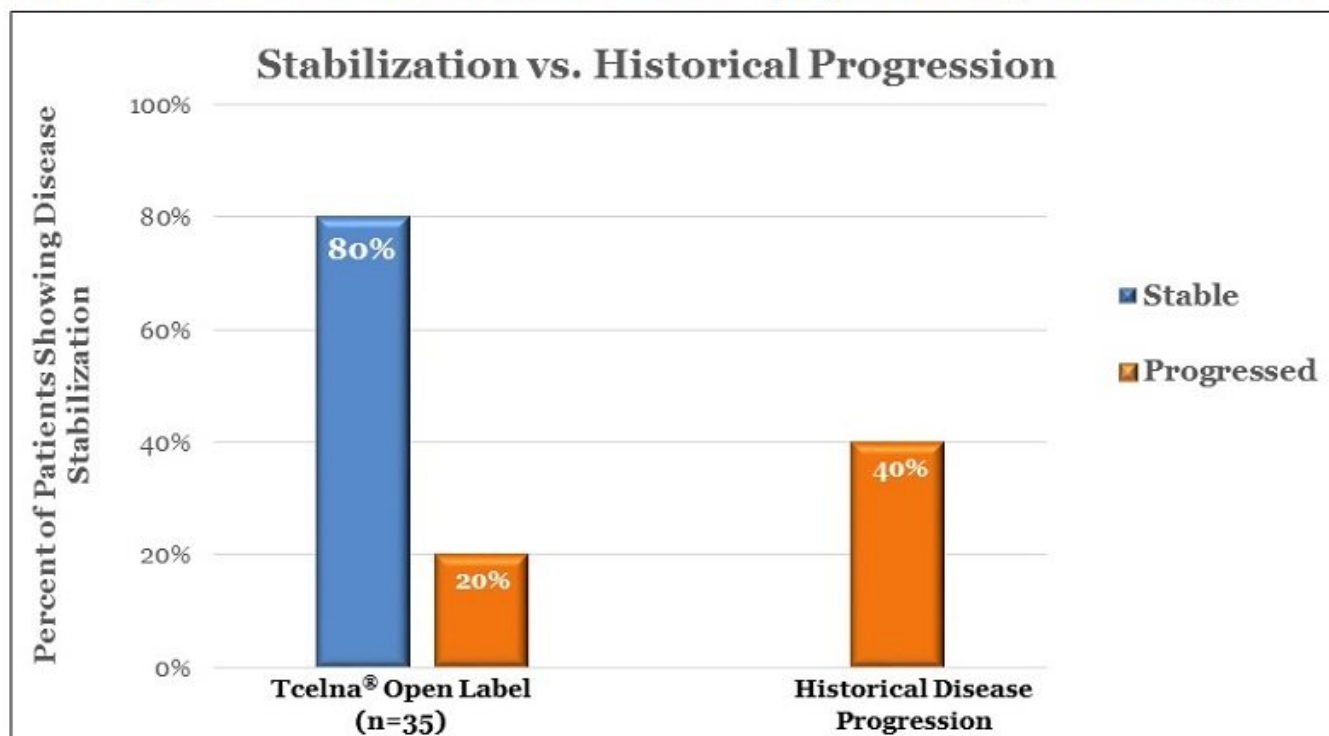


Precision Immunotherapy®

SPMS Patient Data: Previous Studies

Tcelna stabilizes disease in SPMS Patients at 2 years

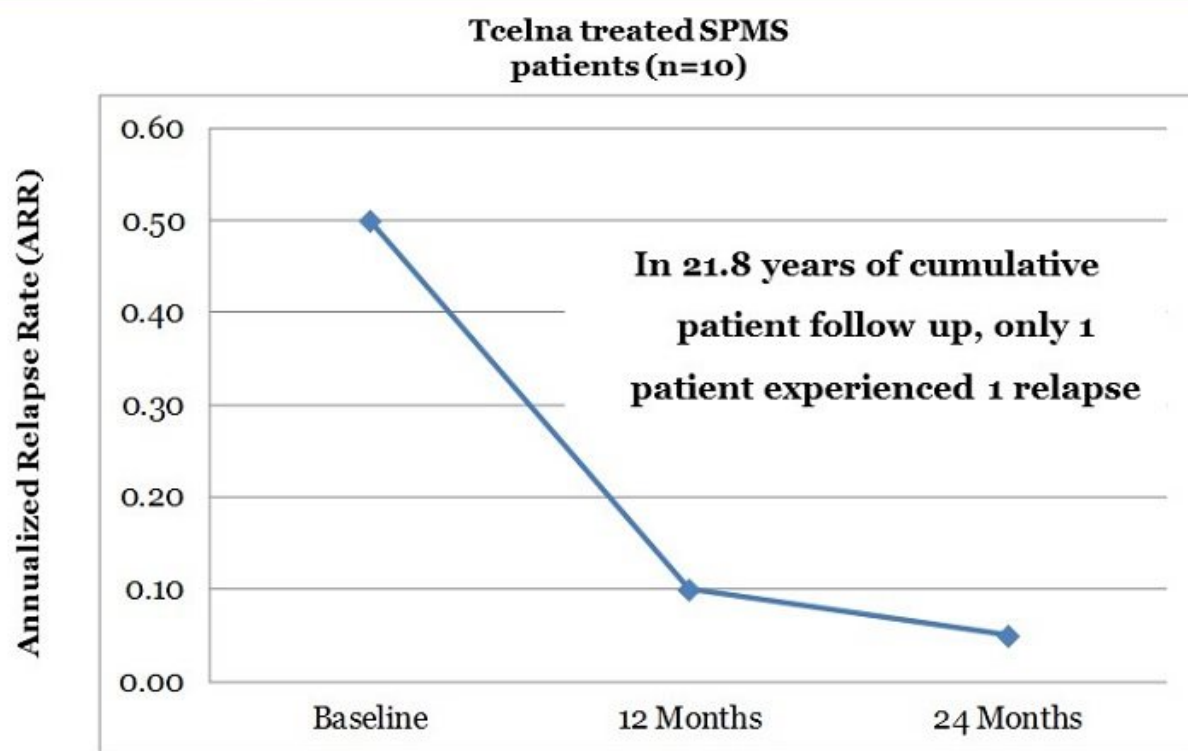
80% of patients showed no further disease progression by EDSS at 2 years



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

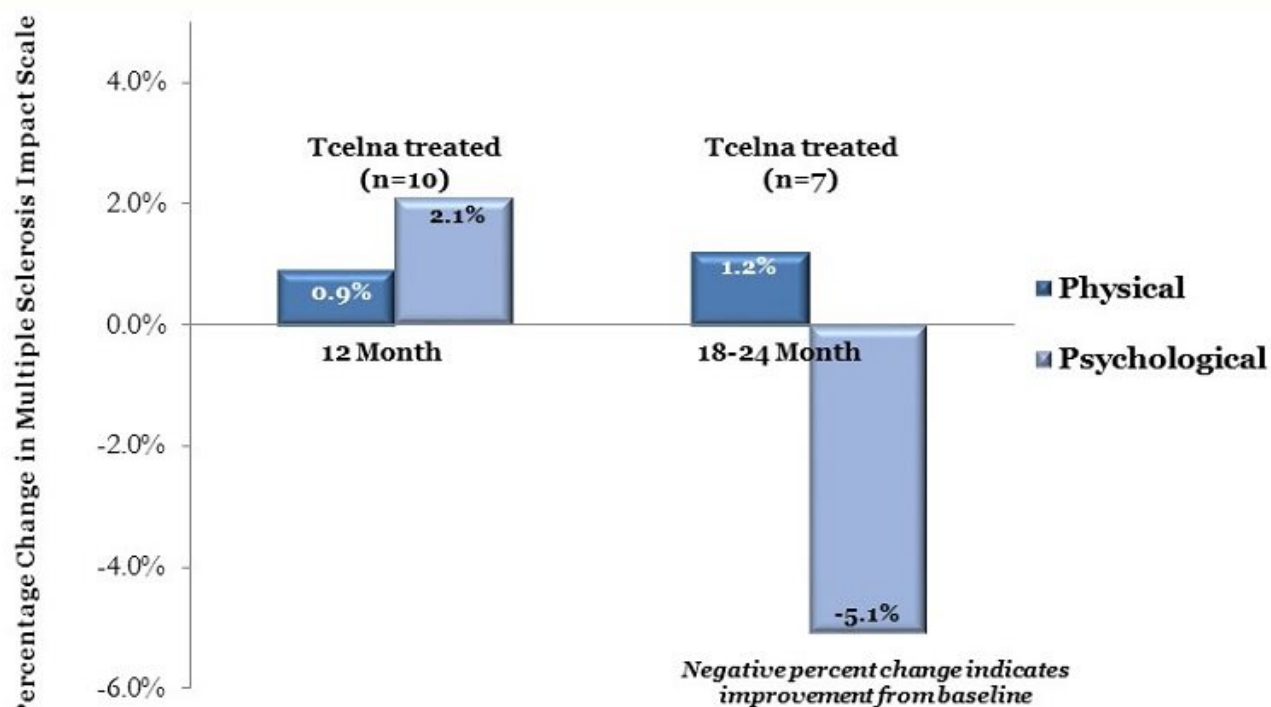
**Historical control: ESIMS Study, published *Hommes Lancet* 2004

Tcelna Reduces Annualized Relapse Rate (ARR) in SPMS at 2 years



One relapse observed in 21 years of cumulative patient follow up

Tcelna Stabilizes Quality of Life Scores in SPMS at 2 years



Following two years of treatment, no worsening of physical condition and improvement in psychological condition



OPEXA THERAPEUTICS

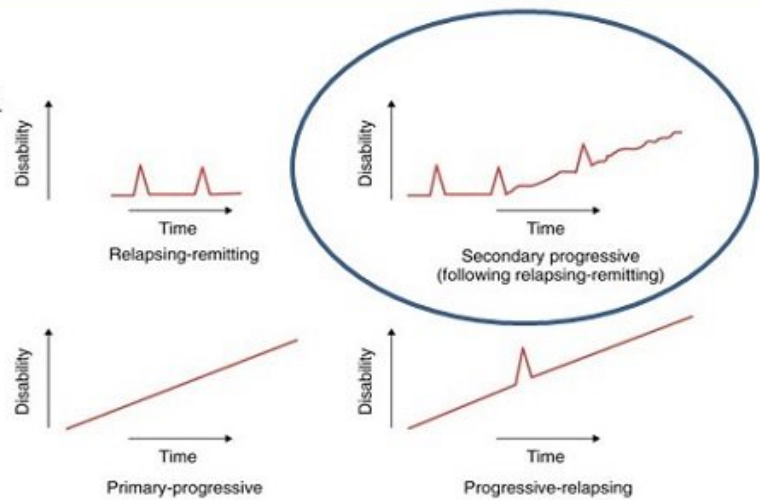
TCELNA[®]: THE STORY



Precision Immunotherapy[®]

Secondary Progressive MS

- Patients initially experience a relapsing-remitting course then transition to SPMS
- SPMS patients experience worsening disability with or without relapses



- Within 10 years of diagnosis, approximately 50% of patients progress to SPMS
- Estimated that 90% of patients will eventually transition to SPMS
- Approximately 30-45% of all MS patients can be classified as SPMS

Reference: National MS Society

The Immunopathology of SPMS: Relevance of Tcelna

- **Compartmentalized CNS inflammatory cells**
 - Persistence of meningeal mononuclear cell infiltrates associated in lymphoid follicular structures
 - Microglia activation suggests ongoing chronic innate immune responses
- **Meningeal follicles close to cortical gray matter lesions suggests that adaptive immune responses involving antibody and complement contribute to progression in SPMS**
- **Chronic myelin-reactive T-cells may be contributing to the development of both innate and adaptive immune responses persisting in the CNS**
- **Tcelna immunotherapy may reduce the drivers of this chronic disease-driving immunity through both peripheral and central regulatory responses**

Proposed Mechanism

- **Attenuated, patient-specific (autologous) myelin reactive T-cells (MRTC)**
 - MRTC expanded *ex vivo* in response to immunodominant peptides of MBP, MOG & PLP
- **Therapeutic SubQ dosing ($30-45 \times 10^6$ cells) stimulates host reactivity to the ‘over-represented’ MRTC inducing a dominant negative ‘regulatory T-cell’ response leading to:**
 - Down-regulation of similar endogenous disease-causing myelin reactive T-cells
 - Up-regulation of regulatory cells (*Foxp3+* and *Tr1* cells) to reduce inflammation and provide possible neuroprotection, should these gain entry to the CNS

Tcelna: Promising Efficacy For SPMS

- Previous studies have shown:
 - Favorable safety
 - Well tolerated treatment
 - Promising efficacy trend in atrophy and progression
- Utilizing meaningful endpoints
 - Predicable measurements; atrophy by MRI
 - Acceptable by FDA; composite progression endpoint
- Personalized therapy versus a broad immunosuppressant
- Opexa is advancing the reality of personalized medicine: targeting an unmet medical need in a substantial market



OPEXA THERAPEUTICS

BEN GREENBERG, M.D., M.H.S.

Associate Professor and the Cain Denius Scholar in Mobility Disorders in the Department of Neurology and Neurotherapeutics at UT Southwestern Medical Center





OPX-212: NEUROMYELITIS OPTICA (NMO)

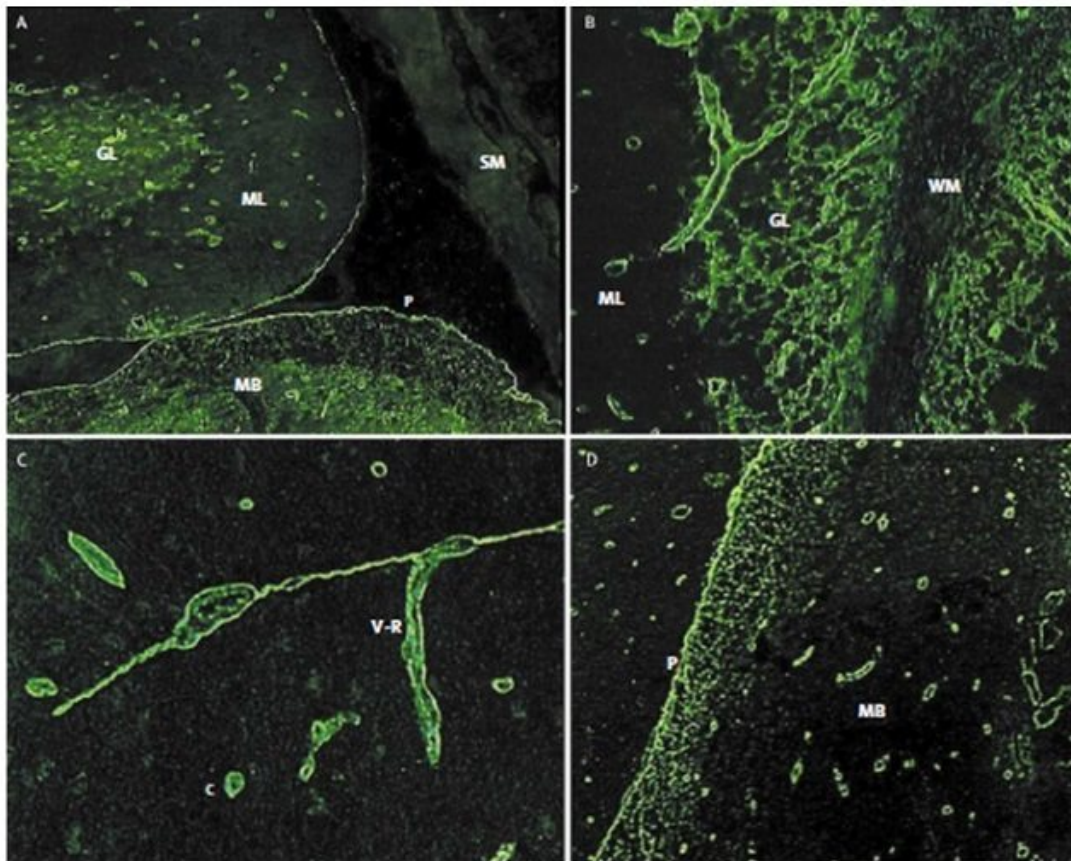


Understanding Neuromyelitis Optica (NMO) in the Context of MS

27 year old woman presents to an ER with 24 hours of difficulty urinating. A foley is placed and one liter of urine is drained from her bladder. Within 12 hours she became weak and ultimately had no motor control of her legs. One year ago she had painful loss of vision in her right eye. She was treated with IV methylprednisilone with partial recovery of vision. Brain MRI and CSF analysis were normal. She was told that the optic neuritis could be a prelude to multiple sclerosis.

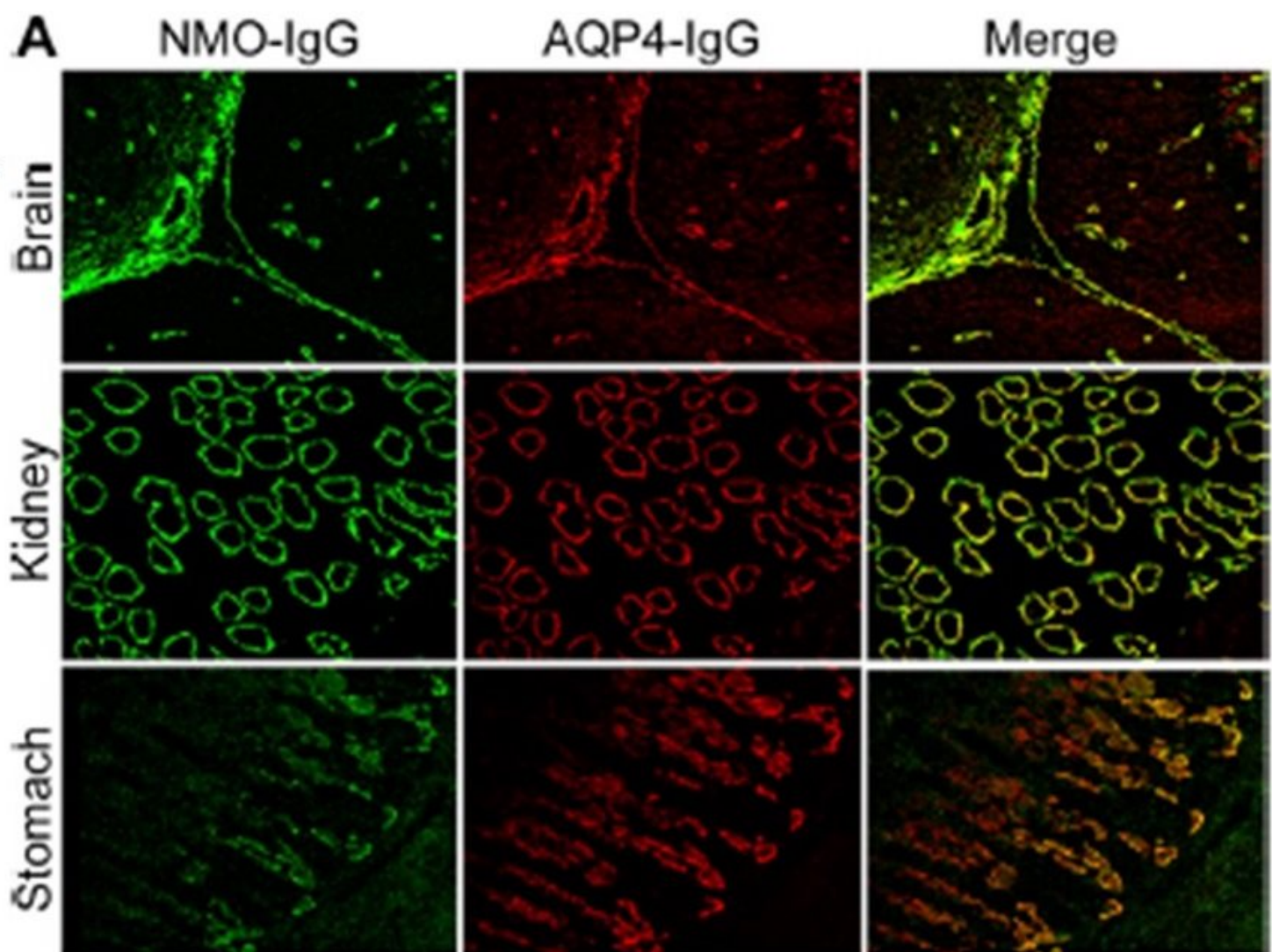


Identifying a Biomarker



Defining the Molecular Basis of Neuromyelitis Optica

- Identify the target of the NMO IgG
- Determine how the biology of the antigenic target relates to the phenotype
- Determine the upstream and downstream components of the disease
 - Antibody mediated tissue destruction versus functional modification of target.



Lennon, et. al., JEM, 2004

Therapeutic Landscape in NMO

- No FDA approved therapies
- All off label use medications are immunosuppressive
- Unique risk-benefit calculations when immunosuppressive is used
- Therapies are universally targeting the B cell mediated component of the condition

Pathways/Treatments being Investigated

- Anti-AQP4 binding interference
 - Small molecule
 - Binding competition
 - B-cell depletion therapy
 - Complement inhibition
 - IL6 inhibition (anti-IL6R)
 - Therapies that interfere with granulocyte recruitment
-
- Future therapies should be based on biologic understanding of disease



Unmet Needs....

NMO AS A T-CELL MEDIATED CONDITION

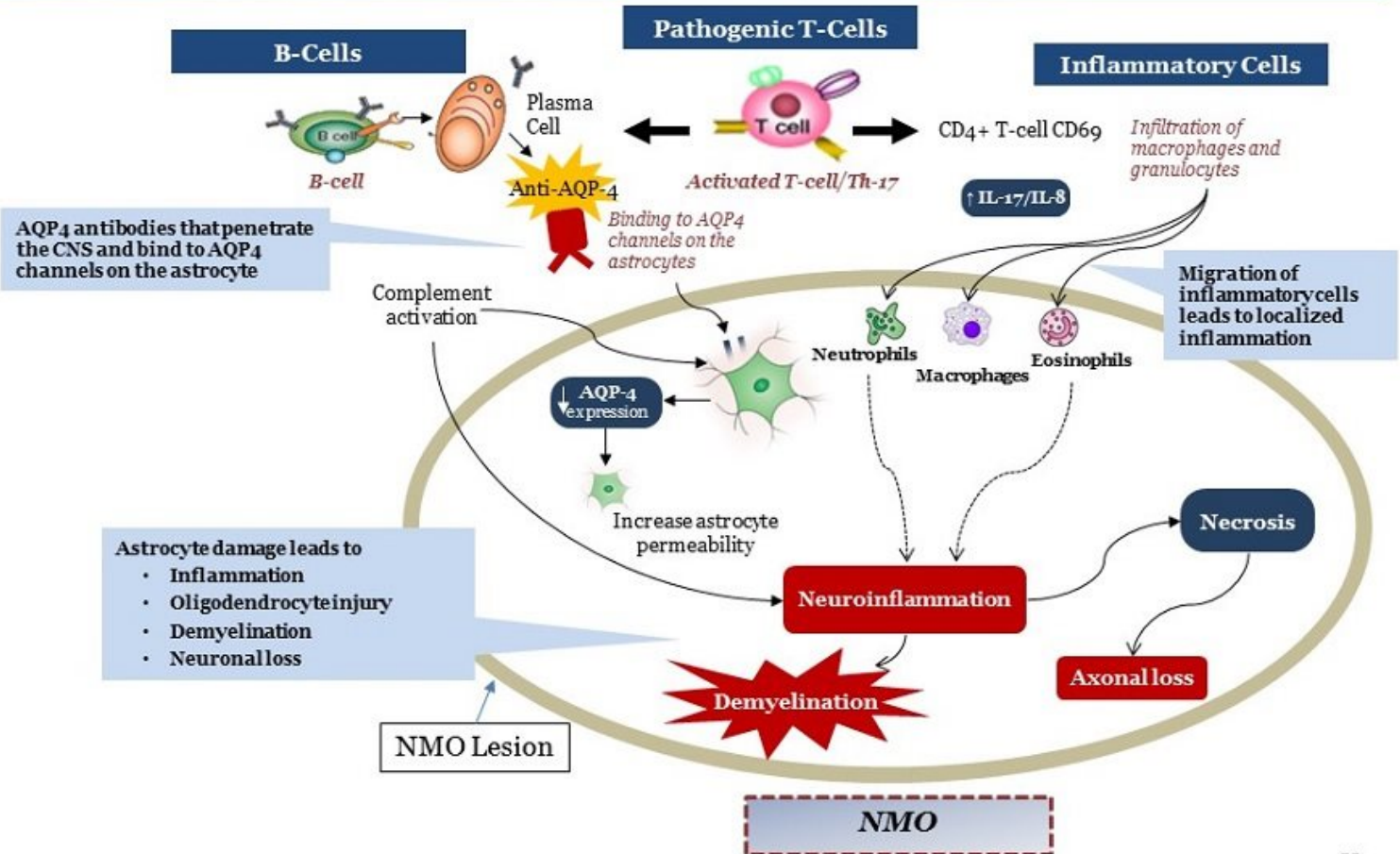


Role for T-cells in Neuromyelitis Optica

1. T cell-activation in neuromyelitis optica lesions plays a role in their formation. Pohl, M *et al.* Acta Neuropathol Commun. 2013;1:85.
2. Immunology of neuromyelitis optica: a T cell-B cell collaboration. Mitsdoerffer, M *et al.* Ann N Y Acad Sci. 2013;1283:57-66
3. Identification of anti-AQP4 T cells in humanized mouse models. Arellano, B., et. al., Arch Neurol. 2012; 69(9):1125-31
4. T/B co-operation in autoantibody production: T cells that promote B-Cell maturation in systemic autoimmunity. Weinstein JS *et al.* Immunol Rev. 2012;247(1):160-71

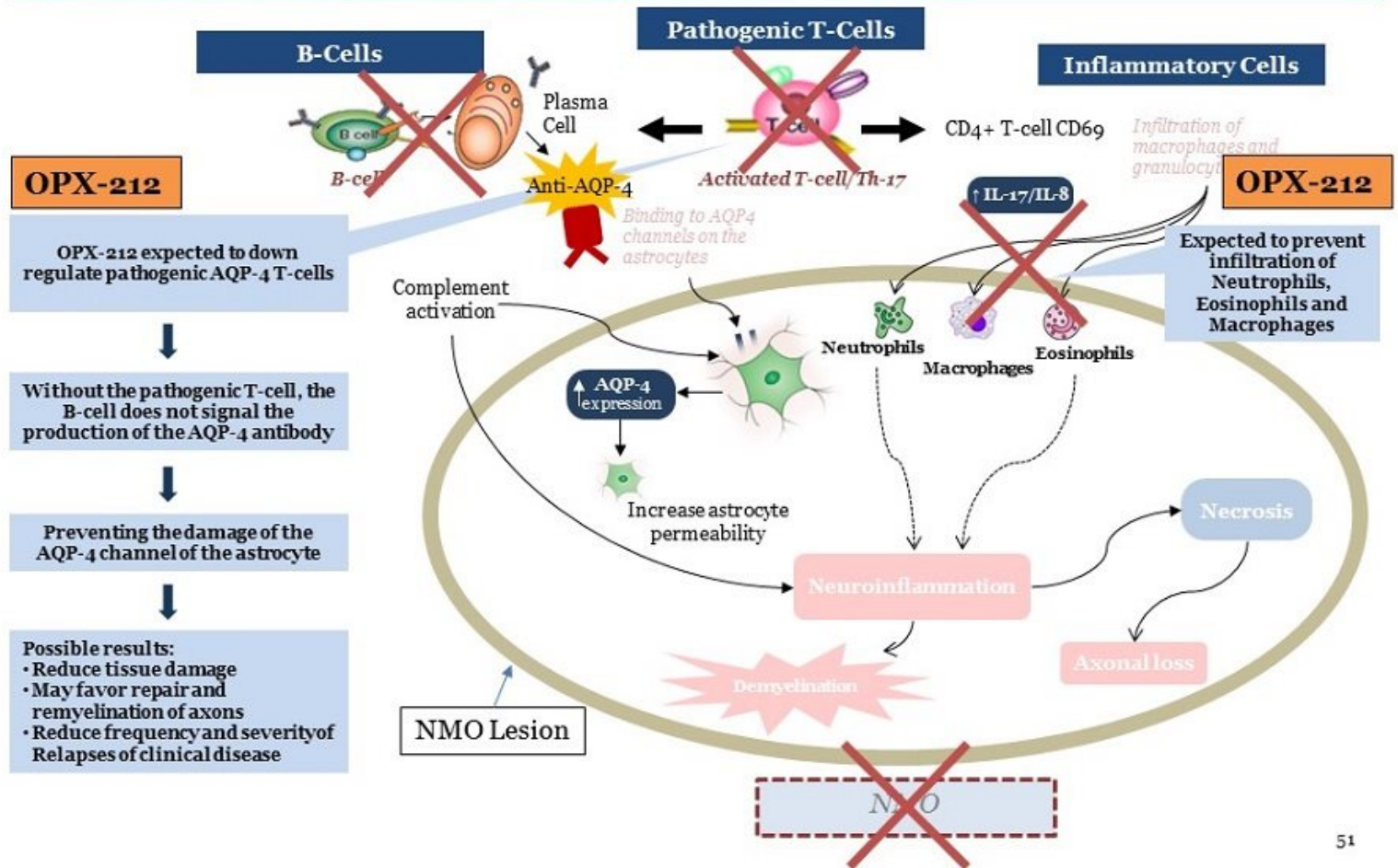
Disease Pathogenesis

An astrocytopathic disease of the CNS characterized by optic neuritis, transverse myelitis; it is a B-cell-dependent disease associated with anti-aquaporin-4 antibodies



Potential Intervention Points for T-cell Therapy

T-cell therapy believed to inhibit AQP-4 autoantibody, pro-inflammatory cytokines and prevent infiltration of macrophages and granulocytes



Meeting unmet needs

- Potentially useful for seropositive and seronegative patients
- Antigen specific
- Personalized medicine
- ***Not overtly immunosuppressive.....
This could potentially change the risk/
benefit calculation dramatically for
patients***

Draft OPX-212.201 Clinical Plan*

- Open-label 3 arm dose escalation study
- Subjects diagnosed with NMSD; + anti-AQP4-Ig
- 20 week treatment period (5 doses: BL, Wk 4, 8, 12, 20)
- 28 week follow up period (48 wk duration)
- Endpoints: safety, reduction in ARTCs
- Estimated first subject enrolled in first half of 2016, assuming the availability of sufficient resources
- Conducted in N. America (US, Canada)
- Key Centers
 - Benjamin Greenberg, MD, MHS – UT Southwestern
 - Michael Levy, MD, PhD – Johns Hopkins
 - Amit Bar-Or, MD – McGill University

(*subject to FDA feedback)



BACK TO NEIL

Recent and Upcoming Expected Milestones

Tcelna: Multiple Sclerosis

- ✓ Q3 2015: 92% of all patient visits in Abili-T trial have been completed
- ✓ Q3 2015: The independent Data and Safety Monitoring Board (DSMB) overseeing Opexa's Abili-T trial met and recommended the trial continue as planned
- 2H 2016: Top line results expected for Abili-T Phase 2b SPMS trial

OPX-212: Neuromyelitis Optica

- ✓ Q3 2015: Secured \$5 million in funding to support OPX-212 NMO development, including Phase I/II proof-of-concept clinical trial, of which \$4.5M is subject to timely satisfaction of milestones
- ✓ Q3 2015: Results of preclinical animal study showed statistically significant dose dependent reduction of AQP4 reactive T-cells in murine (mouse) model
- 1H 2016: Expect to submit IND and be in a position to initiate Phase I/II proof-of-concept clinical trial, assuming the availability of sufficient resources

Recent and Upcoming Expected Milestones

IP

- ✓ Q3 2015: Four additional key patents issued covering T-cell immunotherapy platform
- ✓ 160 total granted U.S. and international patents in Opexa's patent portfolio, including in-licensed patents

Financial (as of Sept 30, 2015)

- ~\$15.6 million cash
- No Debt
- Historical monthly burn: ~\$1.1 million
- Cash runway into Q4 2016
- Shares outstanding ~6.8 million

Opexa Investment Highlights

➤ PIPELINE

- **Tcelna®**: Phase 2b for **secondary progressive multiple sclerosis (SPMS)**, limited competition, \$7BN overall market potential
- **OPX-212**: Pre-IND for **neuromyelitis optica (NMO)**, no approved therapies, **orphan** indication

➤ TECHNOLOGY

- **Personalized T-cell immunotherapy platform** for autoimmune diseases
- Potential to yield multiple candidates tailored to each patient's disease profile
- **Scalable cGMP manufacturing facility**
- Strong patent estate (160 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



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QUESTIONS & ANSWERS



Precision Immunotherapy®

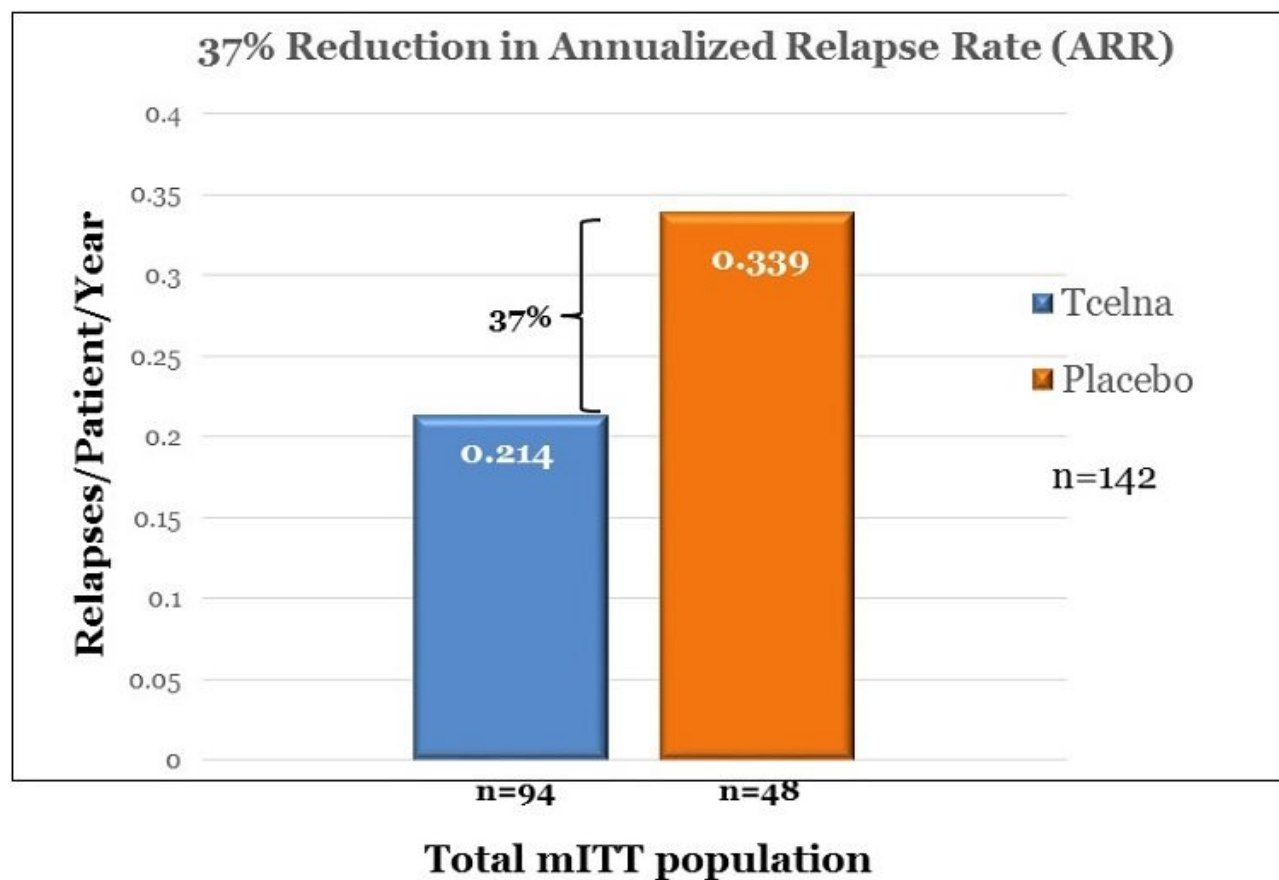


APPENDIX

Phase 2b RRMS prior clinical trial

Tcelna showed 37% improvement over placebo (mITT)

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



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

Jason Kralic, Ph.D., VP, Business Development

- › Former Head of Business Development for the Neurosciences Therapy Area Unit at GlaxoSmithKline
- › Ph.D. in Pharmacology from University of N. Carolina at Chapel Hill School of Medicine

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

Michael S. Richman

Former 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



**Opexa Therapeutics Announces Supportive Preclinical Study Results
for its Neuromyelitis Optica (NMO) Program**

THE WOODLANDS, Texas (November 10, 2015) - Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders including multiple sclerosis (MS) and neuromyelitis optica (NMO), today announced results of a preclinical study, which show that T-cell immunotherapy with attenuated antigen-specific T-cells suppress the T-cell response to Aquaporin-4 (AQP4) in a dose-dependent manner, compared to vehicle control, as measured by reduction in both Aquaporin-4 reactive T-cell (ARTC) proliferation and associated cytokine activity. The results were statistically significant.

In NMO, activated T-cells (ARTC) mount an attack against Aquaporin-4, the autoantigen in NMO, leading to secondary demyelination of nerve fibers within the optic nerves and the spinal cord, resulting in the clinical symptoms of the disease. Opexa's therapeutic approach is to suppress or reduce the number of these activated ARTC in patients with NMO. The results of the preclinical animal study provide evidence that T-cell immunotherapy reduces the level of activated ARTC in a murine (mouse) model.

"The results of the bioactivity study are encouraging as they support our proposed mechanism of action for OPX-212 in NMO," stated Neil K. Warma, Opexa's President and Chief Executive Officer. "NMO is a complex autoimmune disorder and we believe we are unique in developing a targeted and personalized T-cell immunotherapy for this disease which currently has no approved treatments. We believe that OPX-212, by addressing the T-cell component of the disease, may target the root cause of NMO. There is a significant unmet medical need for patients with NMO and this animal study is an important step in our development program for the treatment of patients with this debilitating disease. We are continuing with the preclinical development activities of OPX-212, including completing the manufacturing runs and expect to submit the IND to the U.S. FDA and be in a position to open a Phase 1/2 clinical study in NMO patients in the first half of 2016, assuming the availability of sufficient resources."

"Opexa's T-cell immunotherapy, OPX-212, has an hypothesized mechanism of action to reduce the number of and/or regulate Aquaporin-4 reactive T-cells, thereby reducing the frequency of clinical relapses and subsequent progression in disability," stated Donald Healey, PhD, Opexa's Chief Scientific Officer. "Aquaporin-4 reactive T-cells support pathogenic autoantibody production from B-cells in NMO, but also drive the T-cell mediated cytokine signaling and infiltration of inflammatory cells that also contribute to disease pathology. OPX-212 aims to restore immune tolerance in NMO patients by specifically targeting ARTC while leaving the rest of the patient's immune system intact."

As part of Opexa's preclinical development activities for OPX-212, Opexa conducted a bioactivity study to demonstrate the ability of T-cell immunotherapy using attenuated T-cells to suppress a T-cell response to the NMO-associated autoantigen, AQP4. No animal model of NMO has been described that exhibits both endogenous T-cell dependent immunity and autoantibody production to AQP4 and that subsequently leads to the immunopathology and clinical symptoms observed in human NMO. To study

the bio-activity of attenuated T-cells on AQP4 T-cell immunity, mice were pre-treated with attenuated antigen-specific T-cells and subsequently primed with AQP4 antigen, following which ARTC and associated inflammatory cytokine levels were measured.

NMO, also known as neuromyelitis optica spectrum disorder (NMOSD), is a rare autoimmune disorder, which is designated as an Orphan Disease by the U.S. Food and Drug Administration. There is currently no cure and there are no approved therapies for this disease, worldwide.

About OPX-212

OPX-212 is Opexa's personalized T-cell immunotherapy in development for the treatment of NMO. It will be specifically tailored to each patient's immune response to Aquaporin-4. In NMO, activated T-cells mount an attack against Aquaporin-4, the autoantigen in NMO, leading to secondary demyelination of nerve fibers within the optic nerves and the spinal cord, resulting in the clinical symptoms of the disease. Symptoms of the attack include blindness in one or both eyes followed within days or weeks by varying degrees of paralysis in the arms and legs. OPX-212 has an hypothesized mechanism of action to reduce the number and/or regulate aquaporin-4 reactive T-cells (ARTCs), thereby reducing the frequency of clinical relapses and subsequent progression in disability. OPX-212 will be manufactured using ImmPath[®], Opexa Therapeutics' proprietary T-cell immunotherapy platform technology.

About Opexa

Opexa is a biopharmaceutical company developing a personalized immunotherapy with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases such as neuromyelitis optica (NMO). These therapies are based on Opexa's proprietary T-cell technology. The Company's leading therapy candidate, Tcelna[®], is a personalized T-cell immunotherapy that is in a Phase IIb clinical development program (the Abili-T trial) for the treatment of secondary progressive MS. Tcelna consists of myelin-reactive T-cells, which are expanded ex vivo from the patient's peripheral blood and reintroduced into the same patient in an attenuated form via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin for each individual patient.

For more information, visit the Opexa Therapeutics website at www.opexatherapeutics.com or follow company news on [Twitter](#) via [@OpexaCEO](#).

Cautionary Statement Relating to Forward-Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

Statements contained in this release, other than statements of historical fact, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "expects," "believes," "may," "intends," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that forward-looking statements, including without limitation statements regarding the safety, efficacy and projected development timeline of drug candidates such as Tcelna[®] and OPX-212 constitute forward-looking statements. These 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 in such forward-looking statements as a result of various risks and uncertainties, which include without limitation our ability to raise additional capital to continue our development programs, our ability to successfully develop potential products such as Tcelna and OPX-212, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and OPX-212), as well as other risks associated with the process of discovering, developing and commercializing drug candidates that are safe and effective for use as human therapeutics. These and other risks are described in detail in our SEC filings, including our Annual Report on Form 10-K for the year ended

December 31, 2014 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. All forward-looking statements contained in this release speak only as of the date on which they were first made by us, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after such date.

Company Contact:

Karthik Radhakrishnan

Opexa Therapeutics, Inc.

Chief Financial Officer

281-775-0600

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