



We will begin momentarily at 2pm ET



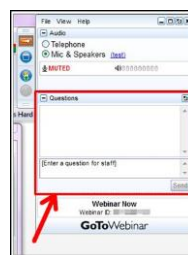
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Western Connecticut State University,
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Thursday, September 7, 2017

Chemistry in Numbers: How to Master the Statistical Analysis of Laboratory Data

Session 8 of the 2017 Industrial Science Series



Stanley Deming, President, Statistical Designs

Stephen Morgan, Professor, Department of Chemistry & Biochemistry, University of South Carolina

Bryan Tweedy, Manager, Office of Career and Professional Resources, American Chemical Society

Thursday, September 14, 2017

How to Create Sustainable Product Design that Satisfies Production Demand and Eco-Awareness

Co-produced with the ACS Green Chemistry Institute



Eric Beckman, Entrepreneur and Bevier Professor of Engineering in the Chemical Engineering Department, University of Pittsburgh

Joseph Fortunak, Professor of Chemistry, Howard University

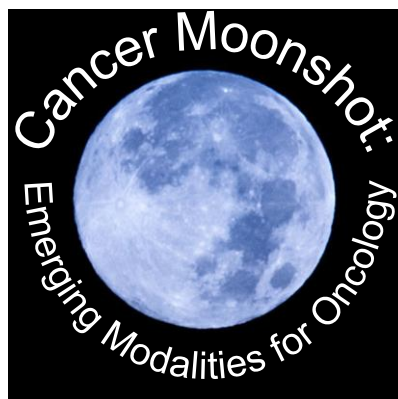
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10

AAPS Annual Meeting – San Diego, CA Nov. 12-15, 2017

Learn about the unique challenges and opportunities in oncology R&D:

- novel targets and data mining
- PK/PD translation
- modality diversity and drug design
- drug delivery & formulation
- regulatory requirements for CMC & safety



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<http://bit.ly/MoonshotAAPS>

11

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12

Catch up on Last Year's Design and Delivery Symposium

	January 28	The Importance of Drug-Target Kinetics in Drug Design Robert Copeland - Epizyme, Inc. Dan Erlanson - Carmot Therapeutics
	February 25	Long-Acting Injectable Medications: Strategies and Mechanistic Considerations Jules Remenar - Alkermes Annette Bak - Merck
	March 31	Modified Release Formulations for Solubility Starved Compounds Mengwei Hu - Merck John Morrison - BMS
	April 28	The Medicinal Chemist of Tomorrow (Special Topic) Joel Barrick - Adillion Ravi Nargund - Merck Molly Schmid - Tech Coast Angels
	May 19	Design of Deliverable Macrocycles Scott Lokley - UC Santa Cruz Nicholas Meanwell - BMS
	June 23	Dreaming Big and Thinking Small: Applying Medicinal Chemistry Strategy to Antibody-Drug Conjugates L. Nathan Sunjey - Pfizer Peter Senter - Seattle Genetics
	July 28	Nucleic Acids Therapeutics: Making Sense of Antisense Oligonucleotides Punit Seth - Ionis Richard Orson - BMS
	August 18	Crystallography as a Drug Design and Delivery Tool (Special Topic) Robert Wenslow - Crystal Pharmatech Vincent Stoll - Abbvie Andrew Brunskill - Merck
	September 29	Dealing with Reactive Drug Metabolites in Drug Discovery: Can We Predict Toxicities of Drug Candidates that form Reactive Metabolites? Deepak Dalka - Pfizer Frederick Peter Guengerich - Vanderbilt University
	October 27	Rational Design of Small Molecules Targeting RNA Matt Disney - Scripps RI Florida Amanda Garner - University of Michigan
	November 10	Cell Penetrating Peptides to Improve Cellular Drug Uptake Dehua Pei - The Ohio State University Scott Hart - Bristol-Myers Squibb



Meet the Organizers



Nicholas Meanwell
BMS



John Morrison
BMS

Co-Produced By



Content Advisors



Richard Connell
Pfizer



Annette Bak
Merck Research Laboratories



Dan Erlanson
Carmot Therapeutics



Mark Tichenor
Janssen Research and Development

<http://bit.ly/2016ddd>

13

2017 Drug Design and Delivery Symposium

Save the Date for the next webinar!



2017 SEPTEMBER						
SUN	MON	TUE	WED	THU	FRI	SAT
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28 	29	30

Meet the Organizers



Nicholas Meanwell
Bristol-Myers Squibb



John Morrison
Bristol-Myers Squibb



Annette Bak
AstraZeneca



Janice Silverman
ACS Publications

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"Immunology: Inflammatory bowel disease"

14

Inaugural Pharma Leaders Symposium

ACS National Meeting in DC
Aug. 21, 2017 - 1 to 4 PM
Walter E. Washington Convention Center - Room 146C



“ACS Pharma Leaders: Working together to make a difference”



- neglected diseases
- chemistry collaborations
- predictive science



abbvie

Speakers:



Genentech
A Member of the Roche Group

Richard Connell of Pfizer
Lisa Shewchuk of GlaxoSmithKline
Bradley Sherborne of Merck
Anil Vasudevan and Dale Kempf of AbbVie
Peter Warner of The Gates Foundation



Organizers: Philip Kym of AbbVie, Catherine Peishoff (formerly of GSK), and Wendy Young of Genentech

For more information, Contact: Susan Ainsworth at s_ainsworth@acs.org

15

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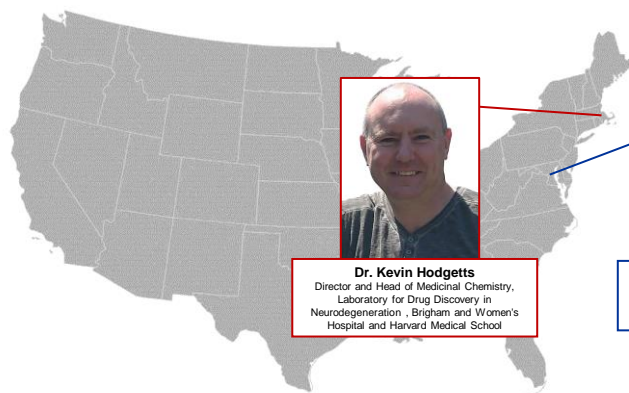
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2017 Drug Design and Delivery Symposium

“Spinal Muscular Atrophy: Novel Approaches for Treatment”



Dr. Kevin Hodgetts
Director and Head of Medicinal Chemistry,
Laboratory for Drug Discovery in
Neurodegeneration, Brigham and Women's
Hospital and Harvard Medical School



Alyson Weidmann
Managing Editor, ACS Chemical
Biology, ACS Chemical
Neuroscience, and Biochemistry

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The 2017 DDDS is co-produced with ACS Division of Medicinal Chemistry and the AAPS 17



Spinal Muscular Atrophy: Novel Approaches for Treatment



Kevin Hodgetts
Laboratory for Drug Discovery in Neurodegeneration
Brigham and Women's Hospital
Cambridge, MA, USA
khodgetts@bwh.harvard.edu

18



Objective



What you will learn ...

- What is Spinal Muscular Atrophy (SMA) and what are the causes
- What is the current SMA Drug Discovery Pipeline
- The medicinal chemistry optimization of molecules that stabilize the survival motor neuron (SMN) protein and increases the transcription of SMN protein



19



What is Spinal Muscular Atrophy (SMA)?



- A neuromuscular disease of infants, children and adults
- Effects both survival and function of the *anterior horn cells* of the spinal cord
- SMA is characterized by progressive muscle weakness
- Leading genetic cause of infant mortality



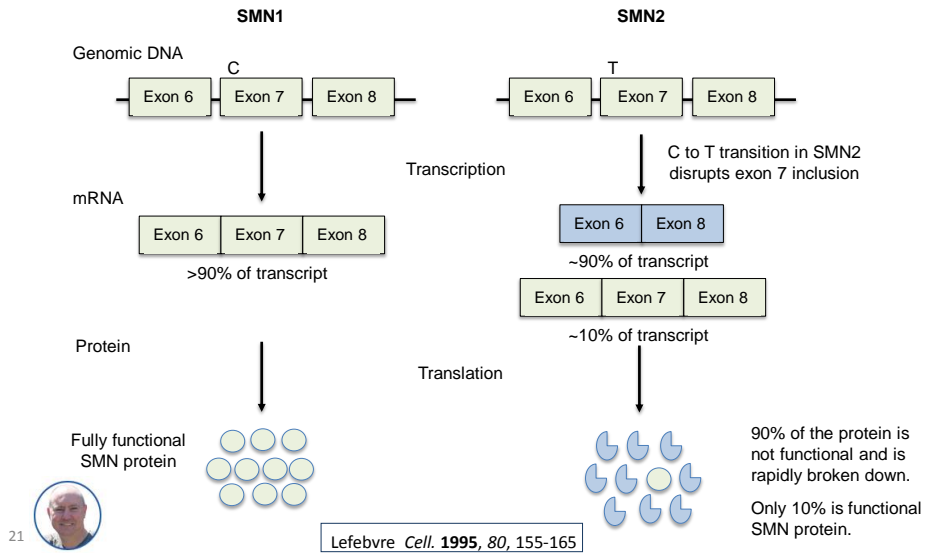
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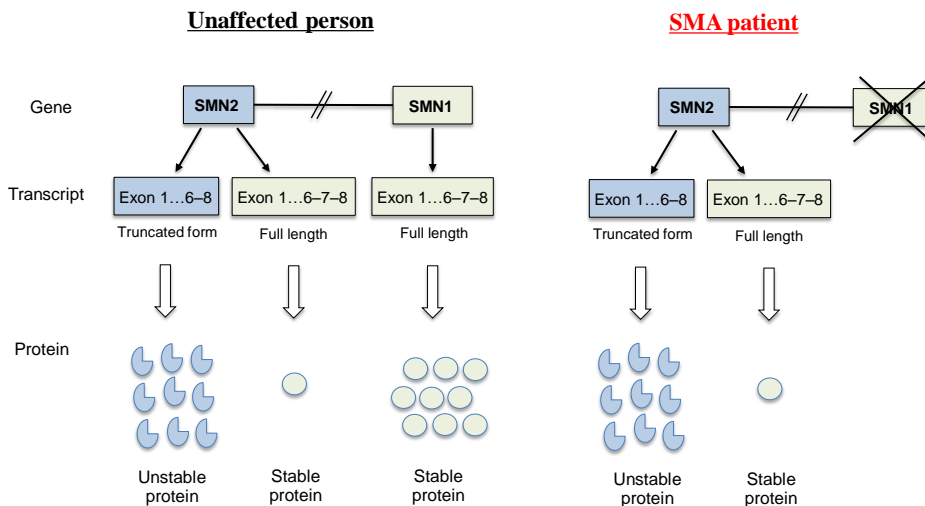
Two genes essential for survival of motor neurons



- Survival of Motor Neuron 1 (*SMN1*) and Survival of Motor Neuron 2 (*SMN2*)



SMA is caused by loss of SMN1 gene



- SMN2* acts as a dose-dependent modifier



SMA is autosomal recessive



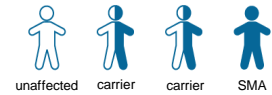
- **SMA results from altered or deleted *SMN1* gene**

- Normal individuals have 2 functional copies of the *SMN1* gene and up to 2 copies of the *SMN2* gene
- Carriers possess 1 functional and 1 altered copy of the *SMN1* gene
- Affected individuals have 0 functional copies of the *SMN1* gene, but multiple copies of the *SMN2* gene

When two carriers have a child



There are 4 possible outcomes



- **Autosomal recessive inheritance pattern**

- Incidence: ~1 in 6,000 - 10,000
- Carrier frequency: ~1 in 50



23



Classifications of SMA



- Categorized by number of *SMN2* copies, age of onset, physical characteristics

SMA Type	Nos of copies of <i>SMN2</i>	Onset	Incidence per live birth (SMA)	Survival	Characteristics
Type 1	2	Before 6 months	~60%	Less than 2-3 years	Will never be able to sit without support
Type 2	3 or 4	6 – 18 months	~27%	68% alive at age 25	Will never be able to walk or stand without support
Type 3	3 or 4	Early childhood	~13%	Normal	Stand alone and walk but may lose this ability in 30s
Type 4	4 to 8	Adulthood	uncommon	Normal	Mild motor impairment

24



Challenge Question

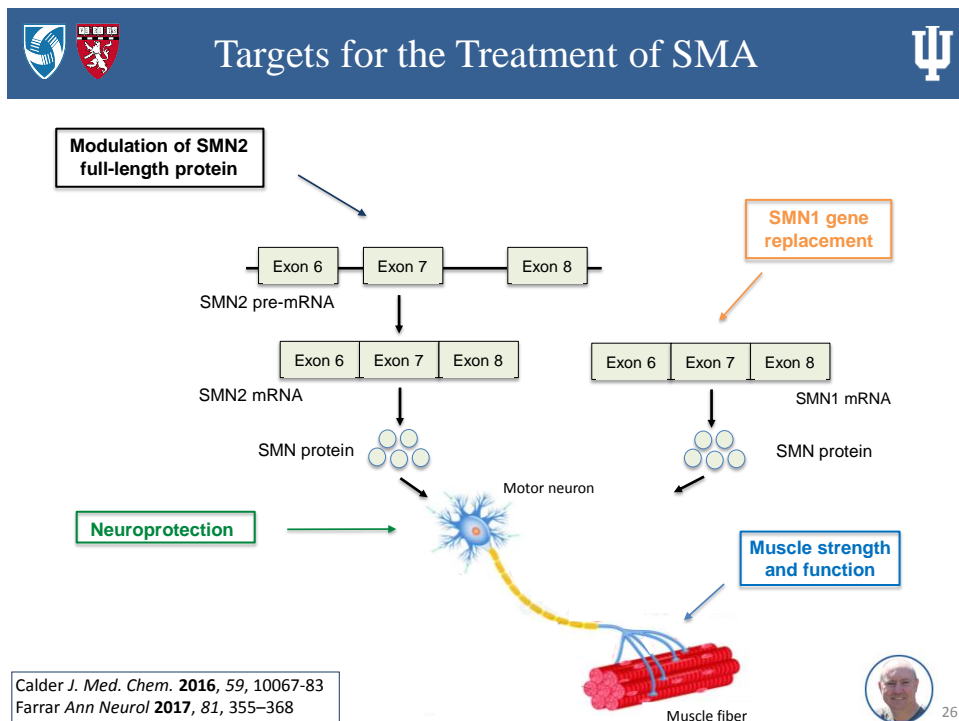
ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

Which of the following statements is TRUE?

(multiple true answers possible)

- SMA does not affect all races and genders
- One child in the USA will die today from SMA
- Everyday, two children in the USA will be diagnosed with SMA
- The survivors of SMA do not require lifelong care and support

25





SMA Drug Development Pipeline



Drug (company)	Phase 1	Phase 2	Phase 3	FDA Approval
Spinraza (Ionis/Biogen)	→			
AVXS-101 (Avexis)	→			
Olesoxime (Roche)	→			
CK-2127107 (Cytokinetics/Astellas)	→			
Pyridostigmine (UMC Utrecht)	→			
4-Aminopyridine (Columbia University)	→			
LMI070 (Novartis)	→			
RG7916 (Roche)	→			

Mode of action

Modulation of SMN2 full-length protein SMN1 gene replacement Neuroprotection Muscle strength and function



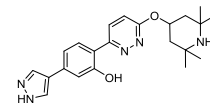
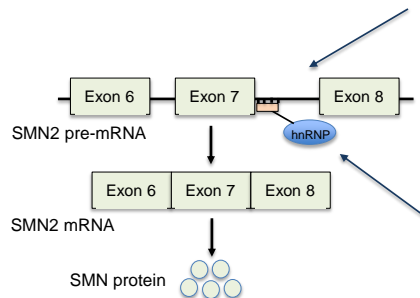
27



Modulation of SMN2



- Splicing modifiers – increased inclusion of exon 7
 - Small molecules: LMI070 (Novartis) and RG7916 (PCT/Roche, structure not disclosed)
 - Antisense oligonucleotide (ASO); Nusinersen (Spinraza™)



LMI070
(NVS-SM1)

LMI070 may interact with the 5' splice site of SMN2 intron 7 and stabilizes its interaction with the U1 small nuclear ribonucleic protein (snRNP) complex

Palacino *Nat. Chem. Biol.* **2015**, *11*, 511-17

Nusinersen (Spinraza™) displaces heterogeneous nuclear ribonucleoprotein (hnRNP) from the intronic splicing silencer site on the SMN2 pre-mRNA

Singh *Mol. Cell Biol.* **2006**, *26*, 1333-46

28

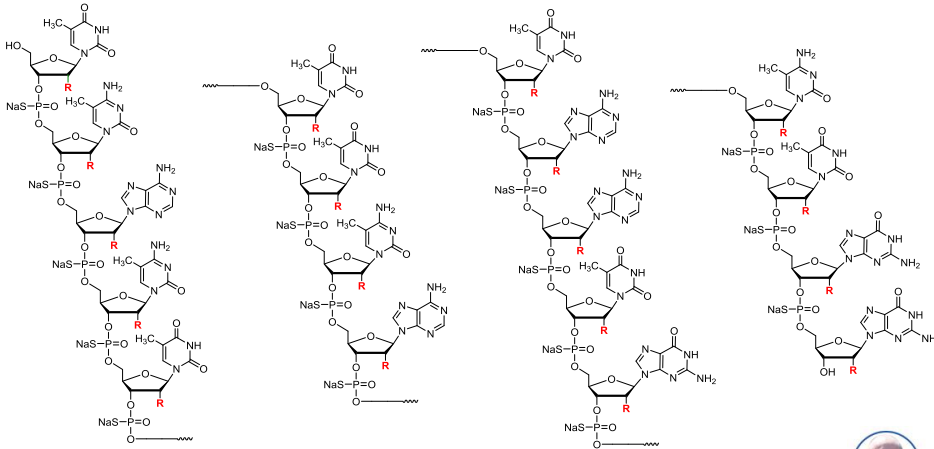
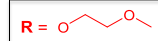




Nusinersen (Spinraza™)



- Antisense Oligonucleotide (ASO)
 - 2'-Methoxyethyl residue (red) protects the oligo from nuclease degradation



29



Discovery and Development



• Academic Discoveries

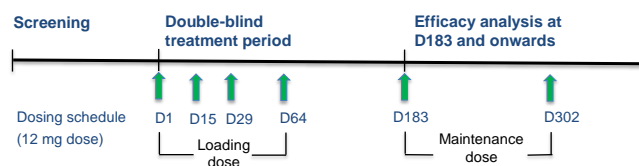
- Drs. Ravindra Singh and Elliot Androphy, formerly at the University of Mass. Medical School (UMMS), identified the *ISSN1* gene sequence targeted in Nusinersen (Cure SMA grant support)
- Dr. Adrian Krainer and colleagues at Cold Spring Harbor Laboratory (CSHL) preclinical development of Nusinersen

• Industry Development

- Ionis Pharmaceuticals licenses intellectual property from CSHL and UMMS
- Phase 1 initiated in December, 2011 – partnered with Biogen in January, 2012

• Phase 3, Ender study of intrathecal Nusinersen in Type 1 SMA babies

- Eligibility; 2 copies of the *SMN2* gene, onset of symptoms ≤ 6 months
- Trial design:



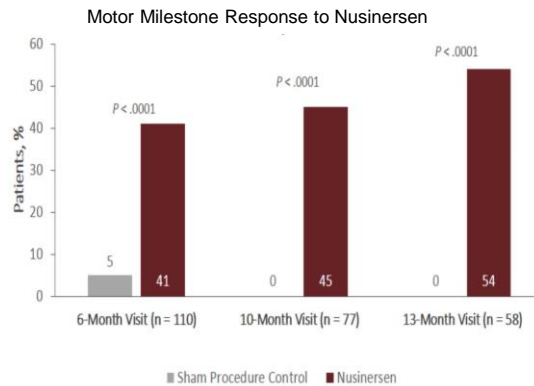
30



Endear Study Results



- **Nusinersen (Spinraza™) was significantly superior to sham lumbar puncture :**
 - Motor milestone response (Hammersmith Infant Neurological Exam, HINE)
 - Event-free survival (death or permanent ventilation)
 - Overall survival



Kuntz AAN 2017, CCI.002

Spinraza™ was approved to treat SMA by the FDA in December, 2016



31

Challenge Question



ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

What is the cost of Spinraza™ per dose?*

- \$1,250 per dose
- \$12,500 per dose
- \$25,000 per dose
- \$125,000 per dose
- It is freely available in the US

* 6 Doses in year 1 and 3 doses per year thereafter

32

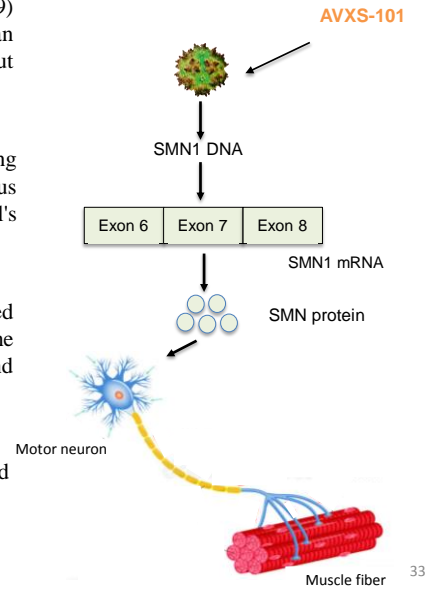


SMN1 gene replacement: AVXS-101



- A non-replicating adeno-associated virus (AAV9) capsid shell delivers a functional copy of a human SMN1 gene to the patient's own cells without modifying the existing DNA of the patient
- Human SMN Transgene: A stable, fully functioning human SMN gene that is introduced into the nucleus of the patient's cells to supplement the cell's production of the SMN protein
- Continuous Promoter: A cytomegalovirus enhanced chicken beta-actin hybrid promoter activates the transgene and designed to allow for continuous and sustained SMN expression
- Discovery and development by Brian Kaspar and colleagues at Ohio State University and AveXis

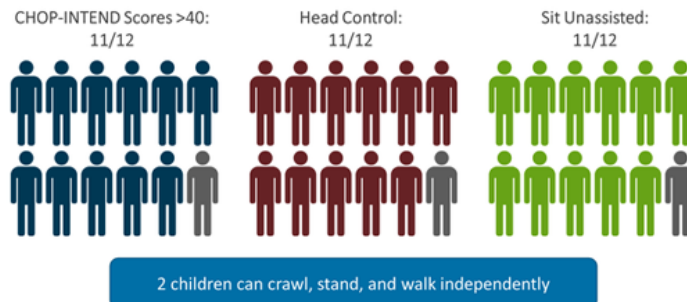
Meyer *Mol Ther.* **2015**, 23, 477-87



Efficacy in Phase 1 Trial of AVXS-101



- Phase 1 clinical trials are very promising



- Early diagnosis and treatment essential

Mendell *Neurology* **2017**; 88 (16 suppl): CT.003



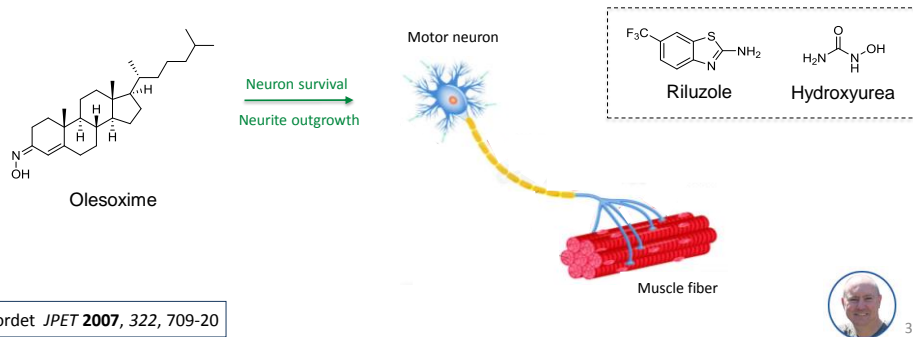
34



Neuroprotection



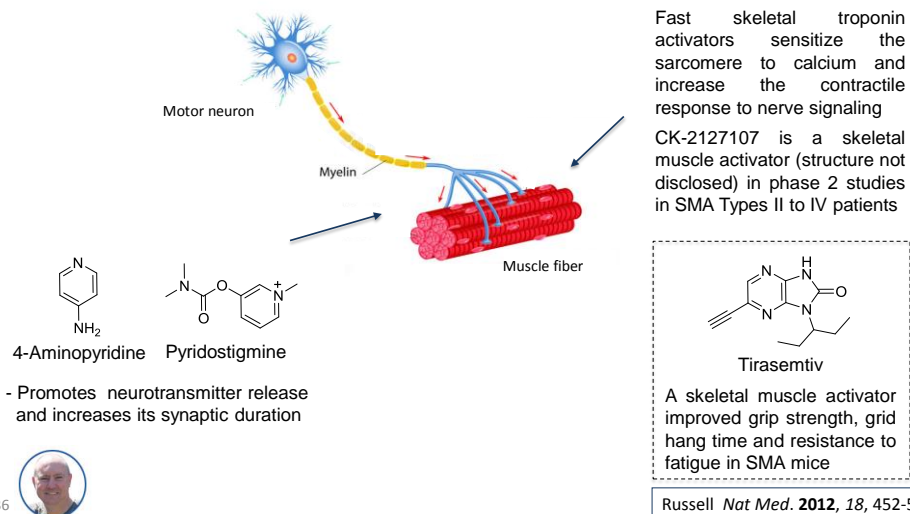
- In SMA, the motor neurons cannot properly function and eventually die, leading to debilitating and often fatal muscle weakness
- Olesoxime is a neuroprotective, discovered by Trophos and licensed to Roche
- In phase 2 studies in patients with Type II or nonambulant Type III SMA, Olesoxime maintained, and in some cases improved, motor function compared with placebo
- Riluzole and hydroxyurea – neuroprotective drugs repurposed for SMA, but are ineffective



Muscle strength and function



- Low levels of SMN disrupt the motor neurons that control muscle function
- The loss of nerve stimulation causes the skeletal muscles to atrophy in SMA





SMA Drug Discovery Pipeline



	Optimization	IND Enabling
BBrm02 – SMN2 – (BioBlast)	→	→
ASO – SMN2 – (OSU/UM)	→	
Small molecule – SMN2 – (Calibr)	→	
Gene therapy (Genzyme)	→	
Gene therapy (Genethon)	→	
SRK-015 – Muscle – (Scholar Rock)	→	→
SMN2 Transcription (IU/LDDN)	→	
SMN2 Stabilization (Spotlight/IU/LDDN)	→	



37

Challenge Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

Why do we still need a pre-clinical SMA Drug Discovery Pipeline? (multiple correct answers possible)

- We don't know how infants receiving Spinraza or AVXS-101 will develop as they age
- The high price and availability of Spinraza and AVXS-101
- The need for therapies for patients with SMA of all types, ages and severities
- There is no need for a pre-clinical SMA Drug Discovery Pipeline

38



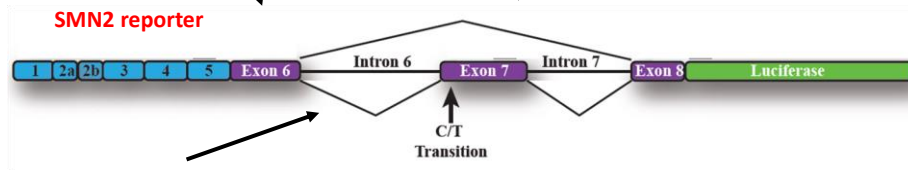
Increasing SMN Protein from the SMN2 gene



2. Increase SMN transcription

1. Increased inclusion of exon 7

Spinraza
PTC/Roche (RG7800, RG7916)
Novartis (LMI070)



3. Stabilization of the SMN protein or RNA

Cherry *J Biomol Screen* 2012, 17, 481-95



39



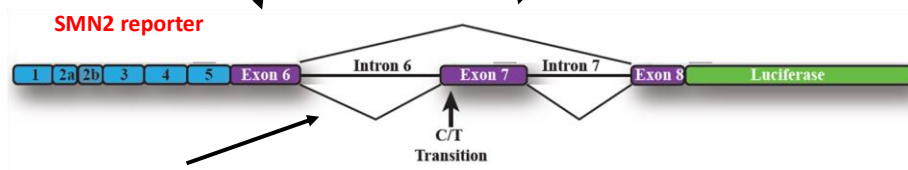
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Novartis (LMI070)



3. Stabilization of the SMN protein or RNA



Cherry *J Biomol Screen* 2012, 17, 481-95



40

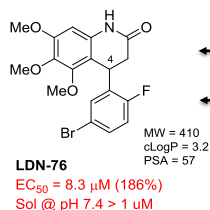


76-Series Preliminary SAR Summary



- Hit from screening

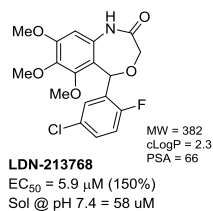
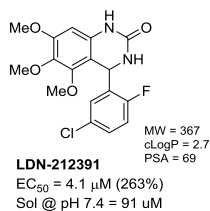
Trimethoxy necessary →



Alternative rings – better
 2,5-Disubstitution – favored
 (2,4-disubstituted – tolerated)



Improved solubility



41



Single Enantiomers

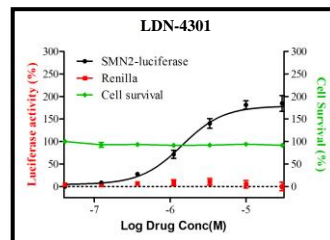
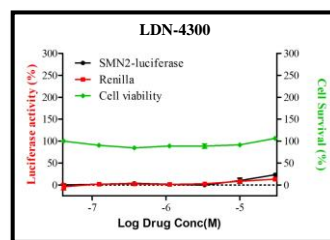
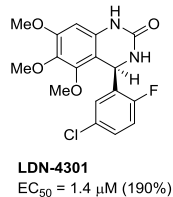
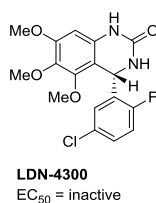


Racemic

Enantiomers



Supercritical fluid
 chromatography
 (Averica, ChiralPaK IC)

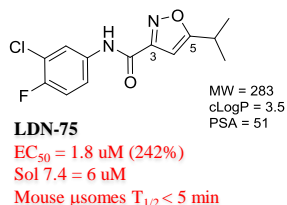


42

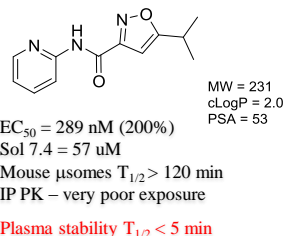
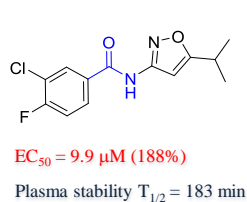
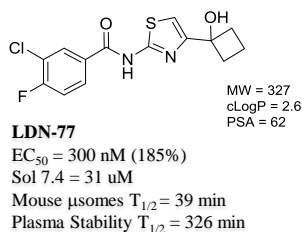
Assignment of stereochemistry is arbitrary – derivatization and X-ray analysis in progress



75-Series Preliminary Optimization



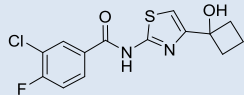
Aryl SAR

Reverse
amideChange
heterocycle

43

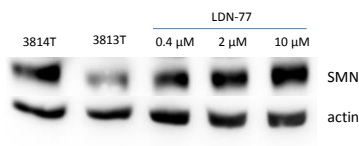


Characterization of LDN-77



LDN-77
 MW = 326, cLogP = 3.7, PSA = 62
 EC₅₀ = 300 nM (185%)
 Sol 7.4 = 31 μ M
 Mouse μ somes T_{1/2} = 39 min
 Plasma Stability T_{1/2} > 120 min

Effect of LDN-77 on SMN protein
levels in fibroblasts

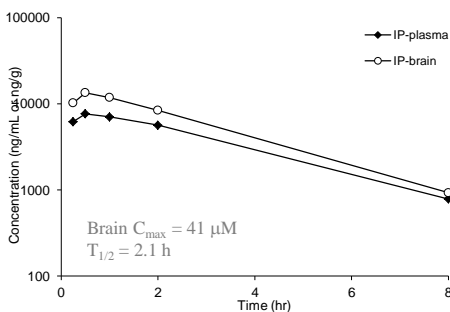


SMA patient fibroblasts (3813T);
normal carrier parental fibroblasts (3814T)

44



Mouse PK of LDN-77 @ 20 mpk IP



No significant effects at 10 μ M

- Broad panel (GPCR, kinases etc)
- Cyp Inhibition (3A4, 2D6, 2C9, 2C19, 1A2)

Mouse PO PK: Moderate oral exposure

Reitz *JMC* 2017, 60, 4594-4610

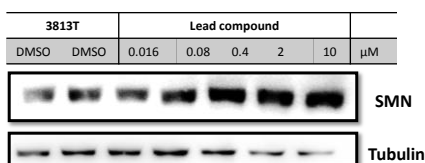


Representative New Lead with Oral Exposure



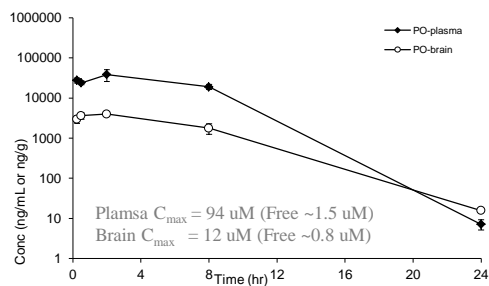
MW = 330, cLogP = 3.4, PSA = 66
 EC₅₀ = 109 nM (200%)
 Sol 7.4 = 58 uM
 Mouse μ somes T_{1/2} = 87 min
 Brain tissue binding = 92.6%
 Plasma protein binding = 98.4%
 MDCK: A-B: 58 x 10⁻⁶
 B-A: 38 x 10⁻⁶ cm/s, ER: 0.8

Effect on SMN protein levels in fibroblasts



45

Mouse PK of lead @ 30 mpk PO



No significant effects at 10 μ M

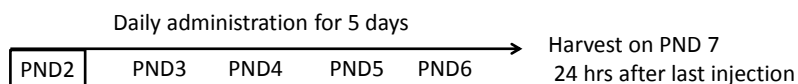
- Broad panel (GPCR, kinases, etc.)
- Cyp Inhibition (3A4, 2D6, 2C9, 2C19, 1A2)
- Cyp Induction (PXR)
- hERG



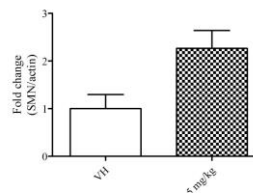
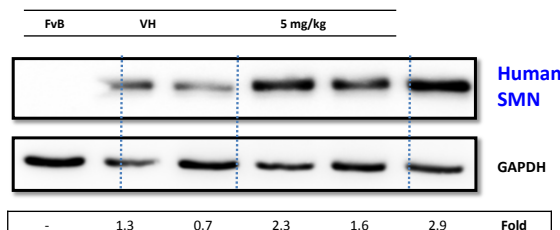
In vivo Effect of lead in 5058 SMA mice



Treatment schedule



Oral dosing (PEG:PBS 50:50)



- This series was recently licensed to SPOTLIGHT INNOVATION
- PK and efficacy studies of the best compounds in Δ 7 SMA mice is in progress



46



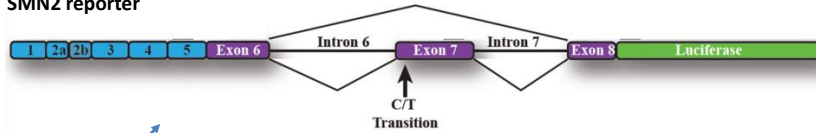
Combination Studies (1): Stabilization and Transcription



SMN transcription

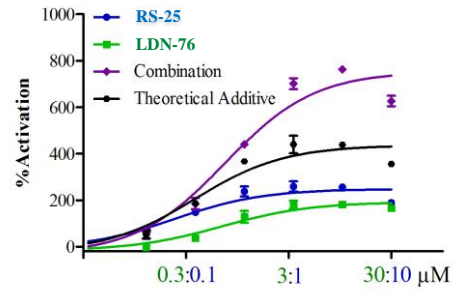
LDN-76
EC₅₀ = 8 μM

SMN2 reporter



RS-25
EC₅₀ = 200 nM

Stabilization of the SMN protein



47



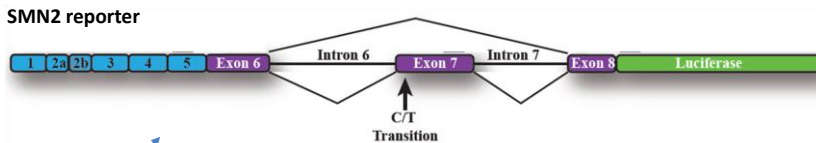
Combination Studies (2) : Stabilization and Splicing



Splicing Modifier

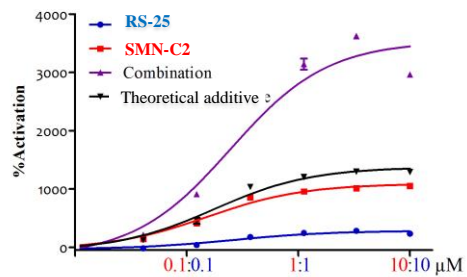
PTC/Roche (SMN-C2)

SMN2 reporter



RS-25
EC₅₀ = 200 nM

Stabilization of the SMN protein



48





Summary



Points we covered ...

- Spinal Muscular Atrophy and its genetics
- Status of the SMA Drug Development and Discovery Pipelines
- Why continued drug discovery research is important
- The medicinal chemistry optimization of molecules that stabilize the survival motor neuron (SMN) protein and increase the SMN protein transcription



Looking Forward



- **How will the infants that received Spinraza™ or AVXS-101 develop as they age?**
- **What will be the prices and availability of Spinraza™ and AVXS-101?**
- **Still need therapies for SMA patients of all ages and severities**
 - Novel mechanisms to modulate SMN, neuroprotection and muscle function
 - Combination therapies
- **Future clinical trials**
 - How will enrollment for new studies be affected?
 - Challenge of the slow rate of disease progression for SMA Types 3 and 4
- **Speed of diagnosis of SMA in newborns**
 - Cure SMA Launched National Newborn Screening Campaign
 - 11th July 2017, Missouri is the First State to Institute Newborn Screening for SMA

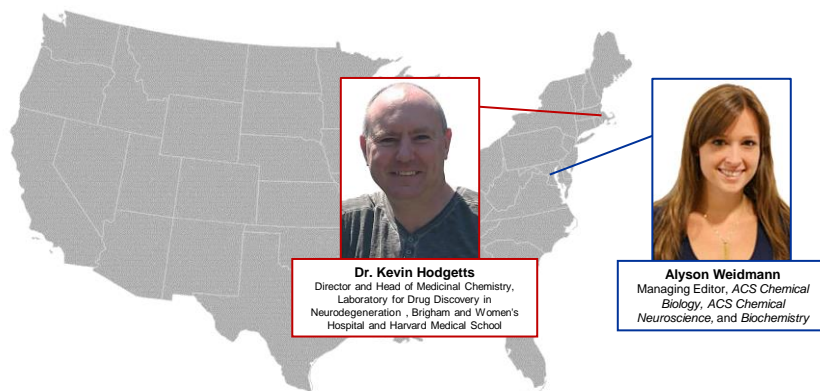


50



2017 Drug Design and Delivery Symposium

"Spinal Muscular Atrophy: Novel Approaches for Treatment"



Dr. Kevin Hodgetts
Director and Head of Medicinal Chemistry,
Laboratory for Drug Discovery in
Neurodegeneration, Brigham and Women's
Hospital and Harvard Medical School

Alyson Weidmann
Managing Editor, ACS Chemical
Biology, ACS Chemical
Neuroscience, and Biochemistry

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Session 8 of the 2017 Industrial Science Series



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Stephen Morgan, Professor, Department of Chemistry & Biochemistry, University of South Carolina

Bryan Tweedy, Manager, Office of Career and Professional Resources, American Chemical Society

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Co-produced with the ACS Green Chemistry Institute



Eric Beckman, Entrepreneur and Bevier Professor of Engineering in the Chemical Engineering Department, University of Pittsburgh

Joseph Fortunak, Professor of Chemistry, Howard University

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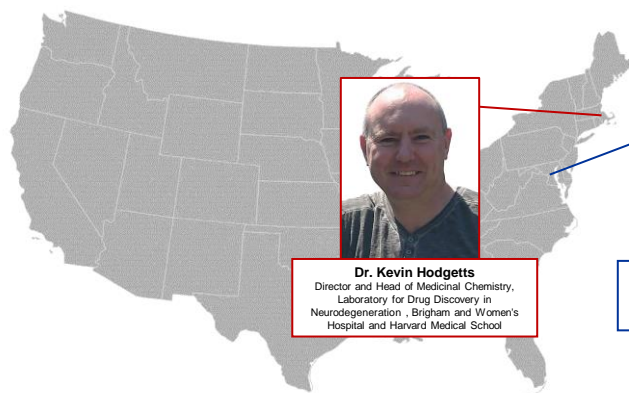
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⁵⁶

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58



59



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62