

Harding University

Scholar Works at Harding

College of Pharmacy Faculty Research and
Publications

College of Pharmacy

Winter 2-10-2016

FDA has a Banner Quarter to Finish Out 2016

Rodney Richmond

Harding University College of Pharmacy, rrichmond@harding.edu

Follow this and additional works at: <https://scholarworks.harding.edu/pharmacy-facpub>



Part of the [Pharmacy Administration, Policy and Regulation Commons](#)

Recommended Citation

Richmond, R. (2016). FDA has a Banner Quarter to Finish Out 2016. *ARRx - The Arkansas Pharmacists*, 15. Retrieved from <https://scholarworks.harding.edu/pharmacy-facpub/29>

This Article is brought to you for free and open access by the College of Pharmacy at Scholar Works at Harding. It has been accepted for inclusion in College of Pharmacy Faculty Research and Publications by an authorized administrator of Scholar Works at Harding. For more information, please contact scholarworks@harding.edu.



HARDING
UNIVERSITY

New Drugs

By Rodney G. Richmond, RPh, MS, CGP, FASCP



FDA Has a Banner Quarter to Finish Out 2015

This column, presented by the Harding University College of Pharmacy, aims to briefly highlight information on new molecular or biological entities, new indications, or significant new dosage forms recently approved by the FDA

The FDA finished out 2015 on a high-note with the approval of 26 new molecular or biological entities and a bevy of significant new drug formulations.

New Dosage Forms: Significant new dosage forms that were approved this quarter include: GenVisc 850® (sodium hyaluronate, injection) for osteoarthritis; Ryzodeg® 70/30 (insulin degludec/aspart, injection) for diabetes mellitus; Dyanavel™ XR (amphetamine, extended-release suspension) for ADHD; Basaglar® (insulin glargine, injection) as a less-expensive biosimilar to Lantus; Narcan® (naloxone, nasal) for suspected opioid overdose; Onivyde™ (irinotecan, liposome injection) for advanced pancreatic cancer; Utibron™ Neohaler® (indacaterol/glycopyrrolate) combination anticholinergic/long-acting beta-agonist for COPD; Seebri™ Neohaler® (glycopyrrolate) anticholinergic for COPD; Durlaza™ (aspirin, extended-release capsule) for secondary prevention of cardiovascular events; Enstilar® (calcipotriene/betamethasone, topical foam) for plaque psoriasis; Belbuca™ (buprenorphine, buccal film) for chronic pain; MorphaBond™ (morphine, extended-

release) for chronic pain; Tolak™ (fluorouracil, cream) for actinic keratosis; Ultravate® (halbetasol, lotion) for plaque psoriasis; and Vivlodex™ (meloxicam, capsules) low-dose for osteoarthritis.

Withdrawals: The FDA withdrew approval for Elepsia™ XR (levetiracetam) due to manufacturing-related regulatory issues.

Losing Patent in 2016: Looking forward to 2016 several highly profitable drugs are going off-patent. Some of the drugs to anticipate include the therapeutic areas of CNS (Intuniv®, Nuvigil®, Seroquel XR™), cardiovascular (Azor®, Benicar®, Crestor®, Tribenzor®, Zetia®), and infectious disease (AmBisome®, Epivir-HBV®, Tygacil®, Epzicom®, Trizivir®, Norvir®, Kaletra®), among others (Aciphex Sprinkles, Advair Diskus, Enablex). §

Contributing Authors:
Jimmy Skaggs, PharmD Candidate
Harding University College of Pharmacy

Brand Name	Review Classification	Indication	Route	Dosing	Est. Average Cost	
Acute Care Products						
Bridion® (sugammadex)	Standard	Neuromuscular blocking drug reversal agent	IV	Single-Dose	-	-
Praxbind® (darucizumab)	Accelerated	Monoclonal antibody reversal agent for Pradaxa	IV	Single-Treatment	\$3,500	Treatment
Chronic Care Products						
Aristada™ (aripiprazole lauroxil)	Standard	Extended-release injection for schizophrenia	IM	Once-Monthly	\$1,900	Month
Fluad™ (influenza vaccine, adjuvanted)	Accelerated	First seasonal influenza vaccine with adjuvant	IM	Annually	-	-
Genvoya® (cobicistat/elvitegravir/emtricitabine/tenofovir)	Standard	Fixed-dose combination for HIV-1 infection	Oral	Once-Daily	\$3,093	Month
Nucala® (mepolizumab)	Standard	Maintenance treatment for severe asthma	SQ	Once-Monthly	\$3,000	Month
Tresiba® (insulin degludec)	Standard	Long-acting insulin analog for diabetes mellitus	SQ	Once-Daily	\$213	Pen
Veltassa™ (patiromer)	Standard	Potassium binder for hyperkalemia	Oral	Once-Daily	\$714	Month
Vraylar™ (cariprazine)	Standard	Schizophrenia; bipolar disorder	Oral	Once-Daily	-	-
Oncology Products						
Alecensa® (alecetinib)	Breakthrough, Priority, Orphan	ALK-positive metastatic non-small cell lung cancer	Oral	Twice-Daily	\$14,793	Month
Cotellic™ (cobimetinib)	Priority, Orphan	Metastatic/unresectable melanoma with mutations	Oral	Cycle	\$2,425	Month
Darzalex™ (daratumumab)	Priority, Orphan	Multiple myeloma refractory to other treatments	IV	Protocol	\$135,550	Year
Empliciti™ (elotuzumab)	Breakthrough, Priority, Orphan	Multiple myeloma refractory to other treatments	IV	Weekly/Biweekly	\$130,000	Year
Imlygic (talimogene laherparepvec)	Standard	First oncolytic virus therapy for unresectable melanoma	Injectable	Variable	\$65,000	Treatment
Lonsurf® (trifluridine/tipiracil)	Standard	Advanced metastatic colorectal cancer	Oral	Cycle	\$3,800	Month
Ninlaro® (ixazomib)	Priority, Orphan	Multiple myeloma in those receiving at least 1 prior therapy	Oral	Cycle	\$10,400	Month
Portrazza™ (necitumumab)	Orphan	Metastatic squamous non-small cell lung cancer	IV	Cycle	\$4,800	Cycle
Tagrisso™ (osimertinib)	Accelerated	Advanced non-small cell lung cancer	Oral	Once-Daily	\$15,300	Month
Vistogard® (uridine triacetate)	Priority, Fast-Track, Orphan	Antidote to fluorouracil or capecitabine chemotherapy	Oral	20 Dose Course	-	-
Yondelis® (trabectedin)	Priority	Metastatic/unresectable liposarcoma or leiomyosarcoma	IV	Cycle	\$7,500	Treatment
Specialty Products						
Adynovate (Antihemophilic factor recombinant)	Standard	Treatment of bleeding in patients with Hemophilia A	IV	On-Demand	-	-
Coagadex® (Coagulation factor X, human)	Priority, Fast-Track, Orphan	Treatment of bleeding in patients with factor X deficiency	IV	On-Demand	\$16,258	Treatment
Kanuma™ (sebelipase alfa)	Breakthrough, Orphan	Lysosomal acid lipase deficiency (Wolman's disease)	IV	Once-Weekly	\$24,000	Week
Nuwiq® (antihemophilic factor, recombinant)	Standard	Treatment of bleeding in patients with Hemophilia A	IV	On-Demand	\$4,800	Dose
Strensiq™ (asfotase alfa)	Breakthrough, Orphan	Perinatal/infantile and juvenile-onset hypophosphatasia	SQ	3-6 Times Weekly	\$552,000	Year
Vonvendi (von Willebrand factor, recombinant)	Orphan	Treatment of bleeding in von Willebrand factor deficiency	IV	On-Demand	-	-

AR·RX

THE ARKANSAS PHARMACIST

WINTER 2016

Award-Winning Quarterly
Publication of the
Arkansas Pharmacists
Association

Appointment- Based Medication Synchronization:

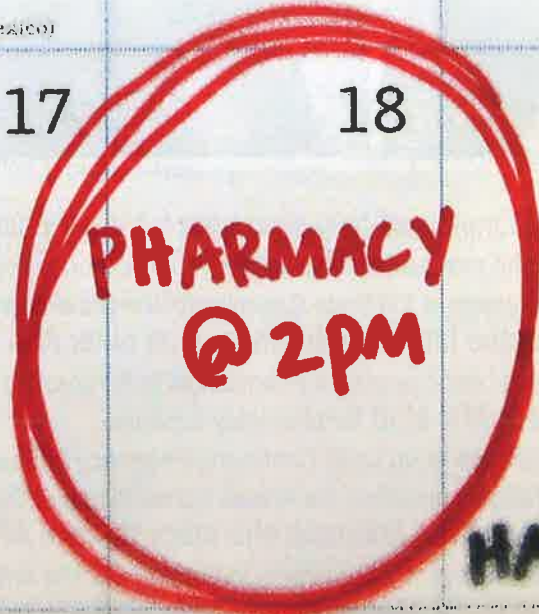
New Study Links ABMS
with Increased Adherence

New UAMS Dean Returns to Arkansas to Lead COP

Mark Riley Bids Farewell to APA



S1 P1 71*****SCH 5-DIGIT 72143
RODNEY RICHMOND
50 COUNTRY CLUB CIR
SEARCY, AR 72143-8901



MOM
B-DAY

BAR ITA

FRAGILE

TUTORING

HAIRCUT

TUTORING

APA Staff

Scott Pace, Pharm.D., J.D.
Executive Vice President and CEO
Scott@arrx.org

Jordan Foster
Director of Communications
Jordan@arrx.org

Susannah Fuquay
Director of Membership & Meetings
Susannah@arrx.org

Celeste Reid
Director of Administrative Services
Celeste@arrx.org

Debra Wolfe
Director of Government Affairs
Debra@arrx.org

Office E-mail Address
Support@arrx.org

Publisher: Scott Pace

Editor: Jordan Foster

Design: Gwen Canfield - Creative Instinct

Arkansas Pharmacists Association
417 South Victory Street
Little Rock, AR 72201-2923
Phone 501-372-5250
Fax 501-372-0546

AR·Rx The Arkansas Pharmacist © (ISSN 0199-3763) is published quarterly by the Arkansas Pharmacists Association, Inc. It is distributed to members as a regular service paid for through allocation of membership dues (\$5.00). Non-members subscription rate is \$30.00 annually. Periodical rate postage paid at Little Rock, AR 72201. Current edition issue number 74.
© 2016 Arkansas Pharmacists Association.

POSTMASTER:

Send address changes to
AR·Rx The Arkansas Pharmacist
417 South Victory
Little Rock, AR 72201

Opinions and statements made by contributors, cartoonists or columnists do not necessarily reflect the attitude of the Association, nor is it responsible for them. All advertisements placed in this publication are subject to the approval of the APA Executive Committee. Visit us on the web at www.arrx.org.



CONTENTS

- 6 **Inside APA:** Moving Forward in a Value-based World
- 7 **From the President:** Leaving A Legacy
- 9 **Member Spotlight:** Rick Rogers, Don's Pharmacy, Little Rock
- 10 **FEATURE:** Life In Sync: The Effects of Medication Synchronization on Patient Non-Adherence
- 13 **Legislator Profile:** Representative John Eubanks - District 74
- 15 **New Drugs:** FDA Has A Banner Quarter to Finish Out 2015
- 17 **Safety Nets:** Legible Doesn't Always Mean Correct
- 18 **Compliance Corner:** Checks and Balances
- 19 **2016 Calendar of Events**
- 20 **FEATURE:** The Same River Twice: Dean Keith Olsen
- 24 **UAMS:** Point-of-Care Testing by Pharmacists
- 25 **Harding:** Harding Graduates Pursuing Residencies Search for Their "Match"
- 26 **AAHP:** Training for Your Career is A Lifelong Effort
- 28 **APA Consultants Academy:** Vitamin D: Should We Put It in the Water?
- 29 **Leaving a Legacy:** Mark Riley Retires As APA CEO (2003 - 2015)
- 34 **Member Classifieds**
- 35 **2016 APA Awards Solicitation**
- 38 **2015-2016 APA Board of Directors**
- 39 **Call for Board Nominations**

DIRECTORY OF ADVERTISERS

- 4 Pace Alliance
- 8 Law Offices of Darren O'Quinn
- 8 Retail Designs, Incorporated
- 14 Pharmacists Mutual
- 16 Pharmacy Quality Commitment
- 23 EPIC Pharmacies
- 23 Arkansas Pharmacy Support Group
- 27 Save the Date: APA Annual 2016 Convention
- 33 Cardinal Health
- 36 UAMS
- 37 Save the Date: 2016 CPE in Paradise
- Back Cover: APA Honors Pharmacy Partners of America