PIPELINE PREVIEW: 2016-2017

A SUMMARY OF THE PHARMACEUTICAL PIPELINE

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INTRODUCTION

DISCLAIMER

Non-biased overview of the pipeline: **Not an all inclusive review of the pipeline**

This CPE program **will** include discussion of non-FDA approved (off-label) medication use

Maria Lowe, Pharm.D., BCPS declares that she has **no** financial relationships with commercial interests. However, her employer, PatientsLikeMe, has received funding from a variety of sources including the following:

Accorda	Biogen Idec	CoPatient	inVentiv Health	Pfizer
Actelion	Boehringer Ingelheim	Curelator	Janssen Pharmaceuticals	Sanofi
Aetna	Bristol-Meyer Squibb	Denali Therapeutics	Merck	Takeda
Alexion	Bupa	EMD Serono	Novartis	Teva
AstraZeneca	Celgene	Genentech	Pathway Genomics	UCB
Avanir Pharmaceuticals	Computer Sciences Corporation	Helsinn	Patient Power	Walgreens

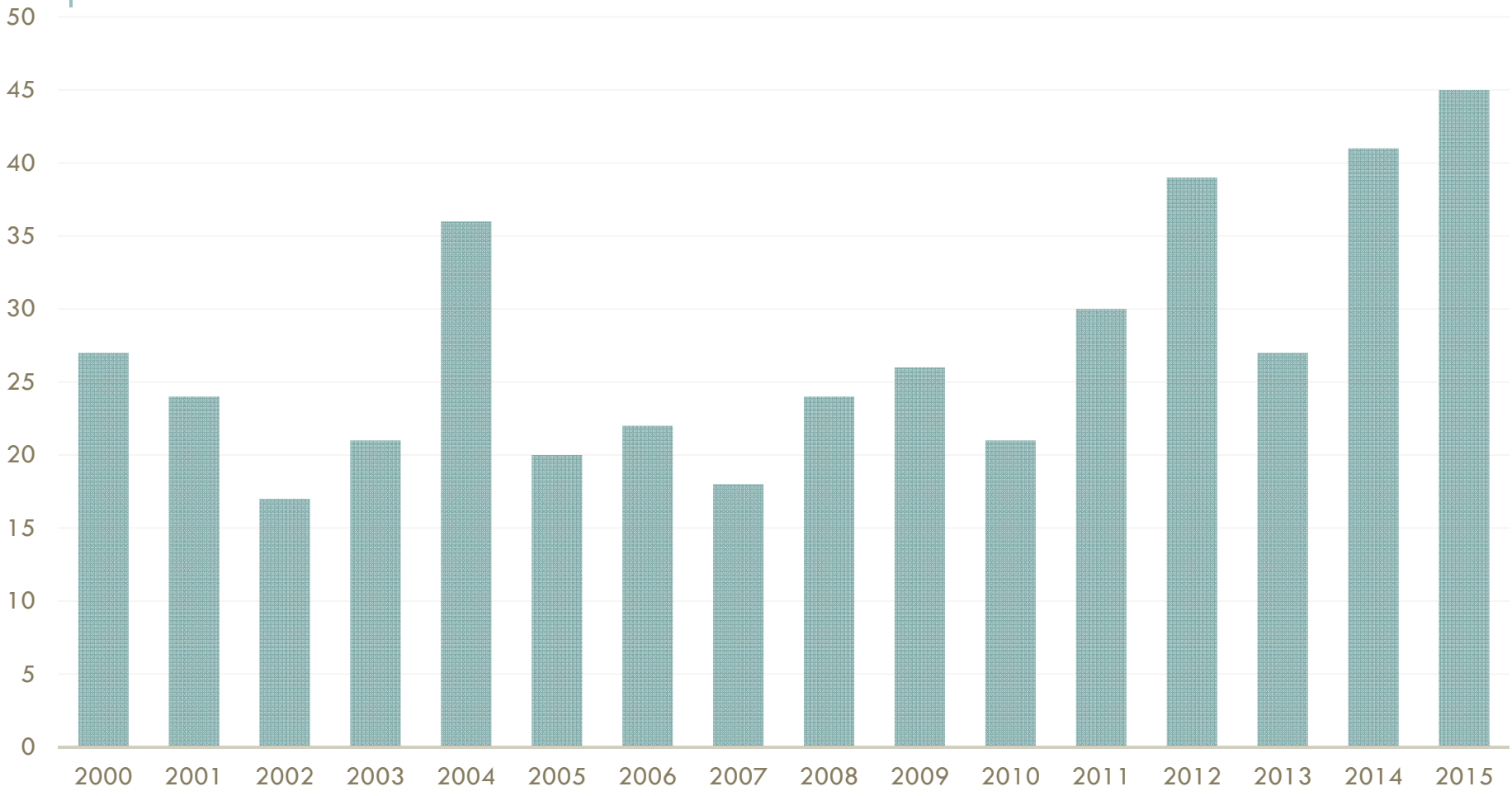
OBJECTIVES

BY THE END OF THIS PRESENTATION YOU WILL BE ABLE TO:

1. Describe recent trends in the FDA approval process
2. Compare and contrast emerging pipeline agents with currently available therapeutic options
3. Summarize the generic availability of commonly used agents over the next two years

PIPELINE TRENDS

FDA APPROVED NEW MOLECULAR ENTITIES



http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ucm121136.htm

TOP AREAS OF CLINICAL DEVELOPMENT

Therapeutic Area	Number of Agents in Development
Anticancer	4,176
Biotechnology	4,051
Neurological	2,513
Anti-infective	2,221
Reformulations	2,080
Alimentary/metabolic	1,999
Musculoskeletal	1,499
Cardiovascular	950
Immunological	869
Respiratory	855

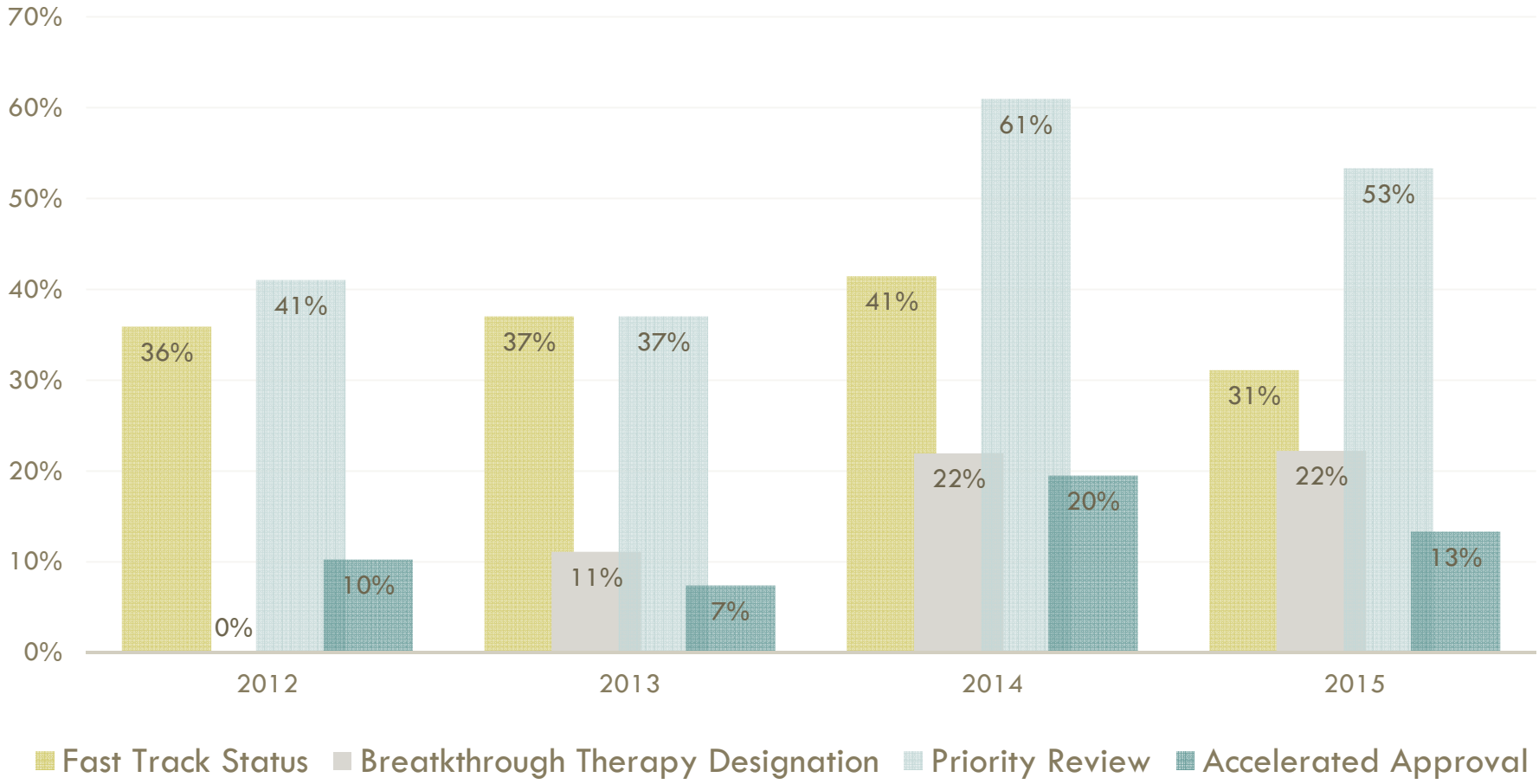
~50% of drugs in development are injectable formulations

~34% of drugs in development are oral formulations

https://citeline.com/wp-content/uploads/Blockbuster-Trends-and-Rising-Stars-of-Global-RD.pdf

PIPELINE TRENDS

USE OF FDA SPECIAL PROGRAMS FOR NMES APPROVED



NME: New molecular entity

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm

TRENDS OF 2016

Clinical Review & Education

JAMA | Special Communication

The High Cost of Prescription Drugs in the United States
Origins and Prospects for Reform

Aaron S. Kesselheim, MD, JD, MPH; Jerry Avorn, MD; Ameet Sarpatwari, JD, PhD

IMPORTANCE The increasing cost of prescription drugs in the United States has become a source of concern for patients, prescribers, payers, and policy makers.

OBJECTIVES To review the origins and effects of high drug prices in the US market and to consider policy options that could contain the cost of prescription drugs.

EVIDENCE We reviewed the peer-reviewed medical and health policy literature from January 2005 to July 2016 for articles addressing the sources of drug prices in the United States, the justifications and consequences of high prices, and possible solutions.

FINDINGS Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index. In 2013, per capita spending on prescription drugs was $858 compared with an average of $400 for 19 other industrialized nations. In the United States, prescription medications now comprise an estimated 17% of overall personal health care services. The most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon Food and Drug Administration approval and by patents. The availability of generic drugs after this exclusivity period is the main means of reducing prices in the United States, but access to them may be delayed by numerous business and legal strategies. The primary counterweight against excessive pricing during market exclusivity is the negotiating power of the payer, which is currently constrained by several factors, including the requirement that most government drug payment plans cover nearly all products. Another key contributor to drug spending is physician prescribing choices when comparable alternatives are available at different costs. Although prices are often justified by the high cost of drug development, there is no evidence of an association between research and development costs and prices; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.

Author Video Interview and Author Audio Interview and JAMA Report Video

CME Quiz at jamanetworkcme.com

JAMA. 2016;316(8):858-71.

Images available from:

http://www.forbes.com/sites/arleneweintraub/2015/02/27/gadfly-pharma-investor-shkreli-starts-anew-after-ousting-from-retrophin/

http://www.mylan.com/en/products/product-catalog/product-profile-page?id=6749373C-9FB4-4E2B-A856-3771B31F68F3

PIPELINE TRENDS

THEMES OF 2016-2017: DISCUSSION

What were some trends in the pipeline that you observed over the last year?

What are the therapeutic categories you feel have the potential for the greatest impact?

ONCOLOGY

PIPELINE TRENDS

Fast-paced area of development: represents approximately 30% of drugs in development

- 2016 has been somewhat slower than recent years
- Last year was a big year for multiple myeloma treatments
- Accelerated approvals: watch for confirmatory trials

Large price tags remain an issue: keep an eye on survival benefit compared to other treatments

- Value of these agents may not always be clear

Immuno-oncology remains a significant area of focus

- Competition is ramping up in lung cancer

ONCOLOGY

GENERIC PIPELINE

Product Name	Anticipated Generic Entry
Aloxi® (palonosetron)	9/2018
Emend® (fosaprepitant injection)	3/2019
Faslodex® (fulvestrant)	3/2019
Sutent® (sunitinib)	2/2021
Tarceva® (erlotinib)	5/2021
Revlimid® (lenalidomide)	3/2022
Alimta® (pemetrexed)	5/2022

Please note: for the purposes of this table, proprietary names are utilized to distinguish patent expiration of the branded product

ONCOLOGY

AGENTS IN DEVELOPMENT: OVARIAN CANCER

Rucaparib

- Oral, twice-daily inhibitor of poly-ADP ribose polymerase-1 (PARP-1)
- Seeking approval for the monotherapy treatment of advanced BRCA+ ovarian cancer after at least two prior treatments
  - ORR **54% (95% CI: 43.8-63.5)**
  - Duration of response **9.2 months (95% CI: 6.6-11.7 months)**
- FDA decision expected **2/23/2017**

Also in development

- Niraparib - NDA submitted 11/1/2016

NDA: new drug application, ORR: objective response rate

ONCOLOGY

AGENTS IN DEVELOPMENT: LUNG CANCER

Brigatinib

- Oral, once-daily inhibitor of ALK and EGFR
- Seeking approval for the treatment of metastatic ALK+ NSLC who have progressed on Xalkori® (crizotinib)
- Phase II ALTA trial:
  - ORR **54%**; median PFS **12.9 months**
  - Intracranial ORR **67%** in patients with measurable brain metastases
- Phase 3 ALTA 1L trial ongoing
  - Brigatinib vs. crizotinib in patients with locally advanced or metastatic ALK+ NSCLC with no prior ALK inhibitor therapy
- FDA decision expected **4/29/2017**

ALK: anaplastic lymphoma kinase, EGFR: epidermal growth factor receptor,
NSCLC: non-small cell lung cancer, ORR: objective response rate, PFS: progression-free survival

ONCOLOGY

AGENTS IN DEVELOPMENT: BREAST CANCER

Ribociclib [LEE011]

- Oral, once-daily inhibitor of cyclin-dependent kinase 4 and 6 (CDK4 & CDK6)
- Seeking approval in conjunction with letrozole as a first-line treatment of postmenopausal women with HR+/HER2- advanced or metastatic breast cancer
- Phase III MONALEESA-2 trial:
  - Ribociclib plus letrozole ↓ the risk of progression or death by **44% (HR = 0.556, 95% CI: 0.429-0.720; P = 0.00000329)** vs. letrozole alone
- FDA decision expected **in the first half of 2017**

HER2: human epidermal growth factor receptor 2, HR: hormone receptor

IMMUNOLOGY

PIPELINE TRENDS

Significant area of focus within pipeline: potential for a number of new product approvals in the first half of 2017

Biosimilars: more products are being approved, but what now?

- Delay in FDA guidance related to interchangeability
- Confusion over when agents will hit the market once approved
- Possible hesitation to prescribe
- Unclear cost-saving potential

IMMUNOLOGY

AGENTS IN DEVELOPMENT

Agent Name	Details	Phase of Development	Also in Development For
Brodalumab	Targets IL-17R	Seeking approval for the treatment of psoriasis FDA decision expected by **11/16/2016**	Psoriatic arthritis, RA
Baricitinib (oral)	JAK1/JAK2 inhibitor	Seeking approval for the treatment of moderately-to-severely active RA FDA decision expected by **1/19/2017**	Atopic dermatitis, SLE
Dupilumab	Targets IL-4R alpha	Seeking approval for the treatment of inadequately controlled moderate-to-severe atopic dermatitis FDA decision expected by **3/29/2017**	Also in development for the treatment of allergic asthma

Please note: all agents are administered subcutaneously unless otherwise indicated

IL: interleukin, JAK: janus kinase, SLE: systemic lupus erythematosus, RA: rheumatoid arthritis

IMMUNOLOGY

AGENTS IN DEVELOPMENT

Agent Name	Details	Phase of Development	Also in Development For
Sirukumab	Targets IL-6	Seeking approval for the treatment of moderately-to-severely active RA BLA submitted **9/2016**	Asthma
Sarilumab	Targets IL-6R	Seeking approval for the treatment of RA **10/2016** FDA declined approval	Non-infectious uveitis
Benralizumab	Targets IL-5Ra	Phase III studies for severe asthma BLA Filing is expected before **end of 2016**	COPD

Please note: all agents are administered subcutaneously unless otherwise indicated

BLA: biologic license application, COPD: chronic obstructive pulmonary disease, IL: interleukin

CARDIOVASCULAR

PIPELINE TRENDS

Lipid lowering and anticoagulant markets are getting crowded: a number of significant approvals in last 18 months

- First antidote for newer oral anticoagulants: Praxbind® (idarucizumab)
- Generic rosuvastatin

PCSK-9 inhibitors are here: now what?

- Focus on cost and place in therapy – pay for performance
- Awaiting outcomes data
- More competition in the lipid-lowering pipeline is yet to come but not from bococizumab

PCSK-9: proprotein convertase subtilisin/kexin-9

CARDIOVASCULAR

GENERIC PIPELINE

Product Name	Anticipated Generic Entry
Azor® (olmesartan/amlodipine)	10/2016
Benicar® (olmesartan)	10/2016[a]
Zetia® (ezetimibe)	12/2016
Aggrenox® (aspirin/dipyridamole)	1/2017
Vytorin® (ezetimibe/simvastatin)	4/2017
Adcirca® (tadalafil)	11/2017

Please note: for the purposes of this table, proprietary names are utilized to distinguish patent expiration of the branded product
a: also includes estimated generic entry of combination with hydrochlorothiazide

CARDIOVASCULAR

AGENTS IN DEVELOPMENT: LIPID-LOWERING THERAPIES

Bempedoic acid [ETC-1002]

- Oral, inhibitor of ATP-citrate lyase
- In development for the treatment of hyperlipidemia
- Phase II trials:
  - ↓ LDL **32-43%** in patients with diabetes
  - ↓ LDL **27-32%** in patients with history of statin intolerance
  - ↓ LDL **43-48%** in combination with Zetia® (ezetimibe)
  - ↓ LDL **22%** when added to atorvastatin 10 mg
- Phase III trials underway
  - Plans for development in fixed-dose combination with ezetimibe

ATP: adenosine triphosphate, LDL: low density lipoprotein

CARDIOVASCULAR

AGENTS IN DEVELOPMENT: ANTICOAGULANT ANTIDOTES

Andexanet alfa (AndexXa®)

- Modified version of Factor Xa which can sequester direct inhibitors
  - Allows native Factor Xa to restore hemostasis
- In development for use as antidote to **betrixaban**, Xarelto® (rivaroxaban), Eliquis® (apixaban), enoxaparin, and Savaysa® (edoxaban)
- FDA declined approval **8/17/2016**

Also in development

- Ciraparantag [PER977] – Phase III

ENDOCRINE

PIPELINE TRENDS

Development across existing classes: focus on new combinations and formulations

- Adlyxin® (lixisenatide) & Jentadueto XR® (linagliptin/metformin ER) approved
- Showdown to become first GLP/insulin combination product

Recent increase in insulin options: effort to make insulin faster and more convenient

- Basaglar® (insulin glargine): expected launch **12/2016**

Safety remains an issue with these agents:

- Ongoing safety concerns related to DPP-4 inhibitors and SGLT2 products
- Cardiovascular **risk reduction** with Victoza® (liraglutide) and Jardiance® (empagliflozin)

DPP-4: dipeptidyl peptidase-4, ER: extended release, GLP: glucagon-like peptide, SGLT2: sodium/glucose co-transporter 2

ENDOCRINE

GENERIC PIPELINE

Product Name	Anticipated Generic Entry
Lantus® (insulin glargine)	2nd Half 2016[a]
Januvia® (sitagliptin)	7/2022
Janumet® (sitagliptin/metformin)	4/2026
Onglyza® (saxagliptin)	11/2028

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a: date when biosimilar/follow-on biologic entry will be allowed, will not be a standard generic

ENDOCRINE

AGENTS IN DEVELOPMENT: ANTI-DIABETICS

Sotagliflozin

- Oral, once daily dual sodium glucose co-transporter 1and 2 inhibitor (SGLT-1 and SGLT-2)
  - SGLT-1 affects glucose absorption in the GI tract
  - SGLT-2 affects glucose absorption in the
- Phase III inTandem1 trial in type 1 diabetes:
  - Average A1C ↓ **0.35%-0.41%** (p<0.001)
  - May potentially reduce meal time insulin needs
- Phase III studies in type 2 diabetes are expected to begin later in 2016

GI: gastrointestinal

ENDOCRINE

AGENTS IN DEVELOPMENT: TYPE 2 DIABETES

Class	Agent Name	Phase of Development	Dosing
GLP-1 Agonists	Semaglutide	Phase III Also in Phase III as oral formulation	SC; Once-weekly Oral formulation: once-daily
	ITCA 650 (exenatide DUROS)	Phase III – NDA expected before end of 2016	SC; Once- or twice-yearly
DPP-4 Inhibitors	Evogliptin	Phase III	Oral, once-daily
	Gosogliptin	Phase III	Oral, once-daily
	Retagliptin	Phase III	Oral, once-daily
SGLT2 Inhibitors	Bexagliflozin	Phase III	Oral, once-daily
	Ertugliflozin	Phase III – NDA expected before end of 2016	Oral, once-daily

DPP-4: dipeptidyl peptidase-4, GLP-1: glucagon-like peptide, NDA: new drug application,
SC: subcutaneous, SGLT2: sodium/glucose co-transporter 2

ENDOCRINE

AGENTS IN DEVELOPMENT: INSULIN

Agent Name	Phase of Development	Dosing
Insulin peglispro	Development terminated	Basal
Faster acting insulin aspart (NN1218)	NDA submitted	Mealtime
MK-1293 *Follow-on biologic insulin glargine*	NDA submitted	Basal
Esysta Bluetooth Insulin Pen	Application submitted	Varies
Buccal insulin spray (Oral-lyn™)	Phase III	Mealtime
BioChaperone® Lispro *In development as U100 and U200*	Phase III planned for 2016	Mealtime
Oral insulin capsule (ORMD-0801)	Phase II	Basal
Oral insulin (Insulin Tregopil)	Phase I	Mealtime

NDA: new drug application

ENDOCRINE

AGENTS IN DEVELOPMENT: COMBINATION PRODUCTS

Agent Name	Phase of Development	Dosing
Saxagliptin/dapagliflozin	10/2015: FDA declined approval	Once-daily
Ertugliflozin/sitagliptin	Phase III	Once-daily
Ertugliflozin/metformin	Phase III	Once-daily
Lixisenatide/insulin glargine (iGlarLixi, LixiLan)	FDA decision expected in 11/2016	Once-daily
Liraglutide/insulin degludec (Xultophy)	FDA decision expected in 12/2016	Once-daily

CENTRAL NERVOUS SYSTEM

PIPELINE TRENDS

Multiple sclerosis: potential treatment for primary progressive disease

Migraine therapy: calcitonin gene related peptides for migraine prevention

- Significant competition to become the first

Pain management: emphasis remains on abuse-deterring opioids

- FDA guidance released: Abuse Deterrent Opioids Evaluation and Labeling
- Priority for new FDA commissioner – outlined a plan for tackling the opioid epidemic

CENTRAL NERVOUS SYSTEM

GENERIC PIPELINE

Product Name	Anticipated Generic Entry
Seroquel XR® (quetiapine ER)	11/2016
Relpax® (eletriptan hydrobromide)	12/2016
Azilect® (rasagiline mesylate)	2/2017
Pristiq® (desvenlafaxine)	3/2017
Strattera® (atomoxetine)	5/2017
Copaxone® (glatiramer acetate)	First half of 2018[a]
Treximet® (sumatriptan/naproxen)	2/2018

Please note: for the purposes of this table, proprietary names are utilized to distinguish patent expiration of the branded product
a: launch date is dependent upon pending patent litigation

ER: extended release

CENTRAL NERVOUS SYSTEM

AGENTS IN DEVELOPMENT: MIGRAINE PREVENTION

Calcitonin gene-related peptides (CGRP)

- Block activity of CGRP to minimize the vasodilation and neuroinflammation that leads to migraines
- First preventative therapy specific to migraines

Phase III	Phase II
Erenumab [AMG334]	TEV-48125
ALD403	MK-8031
Galcanezumab [LY2951742]	

- Acute treatment of migraine
  - Ubrogepant [MK-1602] – Phase III

CENTRAL NERVOUS SYSTEM

AGENTS IN DEVELOPMENT: MULTIPLE SCLEROSIS

Ocrelizumab (Ocrevus™)

- IV, humanized MAB that targets CD-20+ B cells
- Seeking approval for the treatment of relapsing MS and PPMS
- OPERA I and OPERA II Phase III studies in RRMS:
  - ↓ **ARR by ~50%** vs. interferon beta-1a (Rebif®)
- ORATORIO Phase III study in PPMS:
  - ↓ **risk of progression of disability by 24%** vs. placebo
- FDA decision expected **12/28/2016**

ARR: annualized relapse rate, IV: intravenous, MAB: monoclonal antibody, MS: multiple sclerosis
PPMS: primary progressive multiple sclerosis, RRMS: relapsing remitting multiple sclerosis

CENTRAL NERVOUS SYSTEM

AGENTS IN DEVELOPMENT: MULTIPLE SCLEROSIS

Sphingosine-1 phosphate receptor modulators

- Ponesimod
  - Phase III OPTIMUM trial initiated 2015 – head-to-head vs Aubagio® (teriflunomide)
    - Also in Phase II for psoriasis and graft-versus-host disease
- Ozanimod
  - Phase III trials for MS
    - Also in Phase III for ulcerative colitis and Phase II for Crohn's disease
- Siponimod
  - Phase III EXPAND trial for SPMS
    - ↓ **risk of progression of disability by 21%** vs. placebo

MS: multiple sclerosis, SPMS: secondary progressive multiple sclerosis

CENTRAL NERVOUS SYSTEM

AGENTS IN DEVELOPMENT: ABUSE-DETERRING OPIOIDS

Guidance issued in 2015:

- "The FDA is encouraging manufacturers to develop abuse-deterrent drugs that work correctly when taken as prescribed, but, for example, may be formulated in such a way that deters misuse and abuse"
  http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm440713.htm

Abuse-deterrent strategies

- Use of physical and chemical barriers to chewing or crushing
- Use of a sequestered opioid antagonist that is released upon manipulation of the product to neutralize the addictive chemicals
- Ingredients to promote aversion upon misuse
- Delivery systems for non-oral delivery
- Use of chemical entities such as a prodrug

CENTRAL NERVOUS SYSTEM

AGENTS IN DEVELOPMENT: ABUSE-DETERRING OPIOIDS

Opioid Component	Available Products	Agents In Development
Hydrocodone	• Hysingla ER® (hydrocodone bitartrate) • Zohydro ER® (hydrocodone bitartrate)	• AVERSION hydrocodone/APAP (AVERSION H/A) • Apadaz™ (benzhydrocodone hydrochloride and acetaminophen) • ER hydrocodone/APAP [MNK-155] • IR hydrocodone/APAP [TV-46763] • DETERx ER hydrocodone [CEP-33237]
Morphine	• Embeda® (morphine sulfate and naltrexone hydrochloride)	• Arymo® (ER morphine)

APAP: acetaminophen, ER: extended release, IR: immediate release

CENTRAL NERVOUS SYSTEM

AGENTS IN DEVELOPMENT: ABUSE-DETERRING OPIOIDS

Opioid Component	Available Products	Agents In Development
Hydromorphone	• Exalgo® (hydromorphone HCl ER)	• Hydromorphone/naloxone [PRC-062]
Oxycodone	• Oxaydo® (oxycodone HCl IR) • Oxycontin® (oxycodone HCl ER) • Xtampza ER® (oxycodone ER) • Targiniq ER ® (oxycodone and naloxone)	• Oxycodone/naltrexone ER [ALO-02] • Avridi® (IR oxycodone) • Remoxy® (oxycodone ER) • SequestOx® (oxycodone/naltrexone)
Oxymorphone	• Opana ER® (oxymorphone HCl ER)	• N/A

ER: extended release, HCl: hydrochloride, IR: immediate release

INFECTIOUS DISEASES

PIPELINE TRENDS

Hepatitis C DAA market growth: will it slow soon?

- Market has grown quickly and dramatically
- Discontinued production of older agents
- Recent approval of Epclusa® (sofosbuvir and velpatasvir) and Zepatier® (elbasvir and grazoprevir)

Slow progress in the anti-infectives pipeline: few new products despite efforts to encourage development

- Safety update regarding fluoroquinolones

DAA: direct acting antivirals,

INFECTIOUS DISEASES

GENERIC PIPELINE

Product Name	Anticipated Generic Entry
Kaletra® (lopinavir/ritonavir)	12/2016
Norvir® (ritonavir)	12/2016
Prezista® (darunavir)	11/2017
Sustiva® (efavirenz)	12/2017
Reyataz® (atazanavir)	12/2017
Truvada® (emtricitabine/tenofovir)	12/2017
Viread® (tenofovir)	12/2017
Atripla® (efavirenz/emtricitabine/tenofovir)	8/2018

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INFECTIOUS DISEASES

AGENTS IN DEVELOPMENT: HEPATITIS C

Ingredients	Details	Dosing and Duration	Regulatory Status
velpatasvir + sofosbuvir + voxilaprevir	NS5A inhibitor, NS5B polymerase inhibitor, & NS3/4A protease inhibitor	Once daily for 6-12 weeks	Phase III
glecaprevir + pibrentasvir	NS3/4 protease inhibitor & NS5A inhibitor	Once daily for 8-12 weeks	Phase III
grazoprevir + elbasvir* + MK-3682	NS3/4A protease inhibitor, NS5A inhibitor & NS5B polymerase inhibitor	Once daily for 8 weeks	Phase II
odalasvir + AL-335 +simeprevir	NS5A inhibitor, NS5B polymerase inhibitor, & NS3/4A protease inhibitor	Once daily for 6-8 weeks	Phase II

*also in development with MK-8408, an enhanced version of elbasvir

INFECTIOUS DISEASES

AGENTS IN DEVELOPMENT: ANTI-INFECTIVES

2015 National Action Plan for Combating Antibiotic-resistant Bacteria: sets forth the goal of accelerating the research and development of new antibiotics and/or related products

Agents in development include:

- Meropenem-vaborbactam (Carbavance®)
- Delafloxacin
- Eravacycline
- Solithromycin
- Plazomycin
- Fusidic acid (Taksta™)
- Omadacycline
- Iclaprim
- Lefamulin

https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf

IS THAT ALL?

MISCELLANEOUS AGENTS

Nonalcoholic steatohepatitis (NASH)

- Goal of treatment is to prevent advanced fibrosis, cirrhosis, and hepatocellular carcinoma
  - Clinical trials may use surrogate endpoint: impact on steatohepatitis and impact on fibrosis progression
- Highly competitive area of development

Phase III	Phase II
Elafibranor	Simtuzumab
Ocalvia® (obeticholic acid)	Cenicriviroc
Aramchol	Emricasan
Oltipraz [PMK-N01GI1]	GS-4997

PIPELINE TRENDS

THEMES OF 2016-2017: DISCUSSION

What were some trends in the pipeline that you observed over the last year?

What are the therapeutic categories you feel have the potential for the greatest impact?

PIPELINE TRENDS

CONCLUSION

Oncology and immunology: expect these pipelines to continue to move quickly

Diabetes treatment space is getting crowded: keep an eye on insulin products and new combinations

Lots of excitement in the CNS pipeline: specifically with migraine prevention

HCV development continues: next round of products might further shorten treatment, but is the end in sight?

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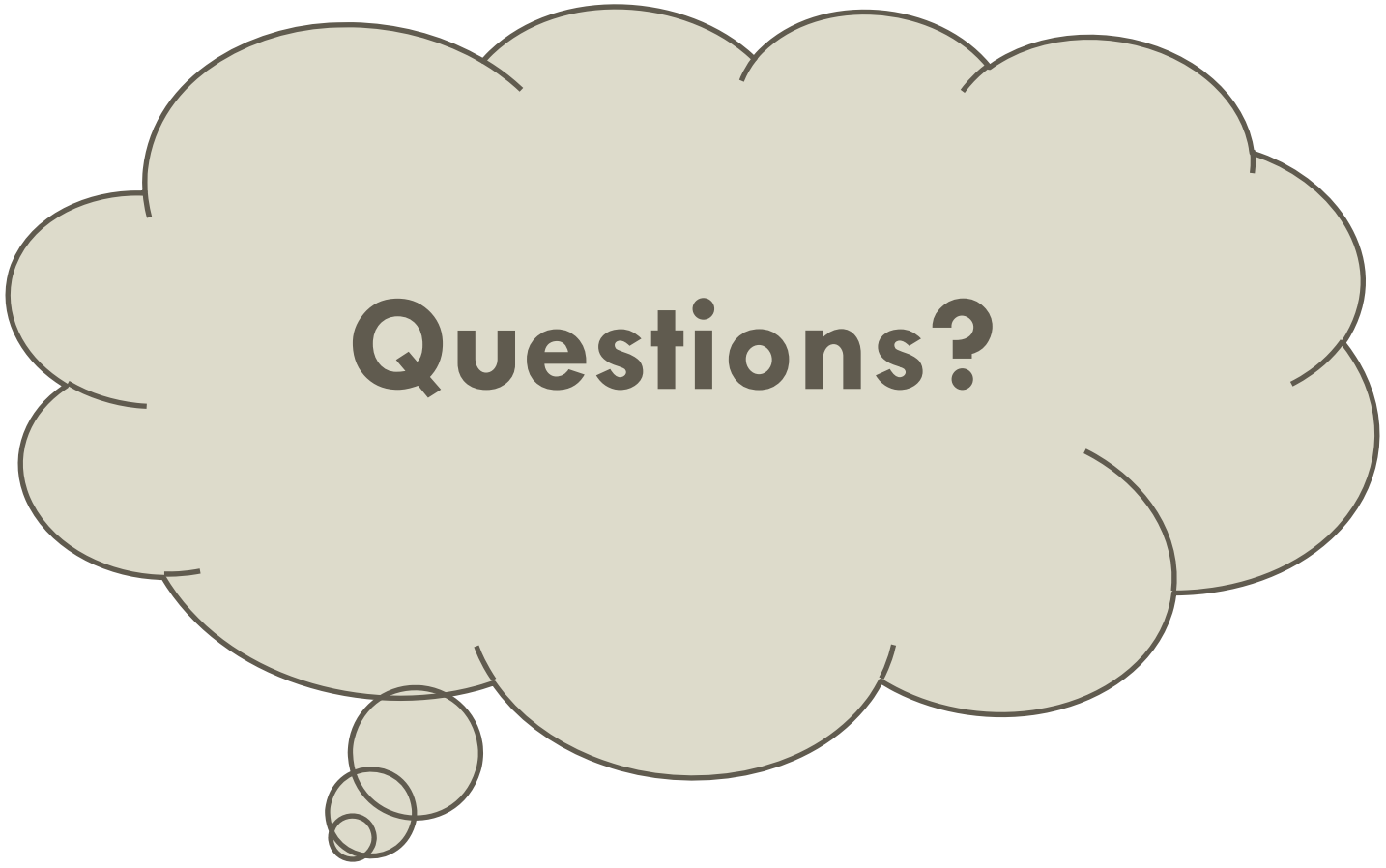
Questions?