Maxor
SPECIALTY PHARMACY

Specialty Pipeline Trends
PART 1 OF 3

Understanding the Specialty Pipeline for Emerging Business Models

WEBINAR SERIES

MEET OUR SPEAKERS

Jessie Heaton, PharmD, MBA, CSP is the Vice President of Specialty and Infusion for Maxor Specialty Pharmacy. He earned his Doctor of Pharmacy degree from Texas Tech University Health Sciences Center. With over 20 years of experience, as well as being a registered pharmacist in 19 states, Jessie is a well versed industry expert with extensive knowledge of accreditation and regulatory requirements for clinical specialty/infusion pharmacy services. He also has detailed knowledge of specialty pharmacy operations, specialty pipeline products and manufacturer requirements needed to obtain access to those products and build centers of excellence around rare and orphan diseases. As a leader at Maxor he encourages his team to follow the motto of "putting our patients at the center of all that we do" to ensure those they serve daily receive excellent care within the centers of excellence he has worked tirelessly to create over his past 13 years with the company.

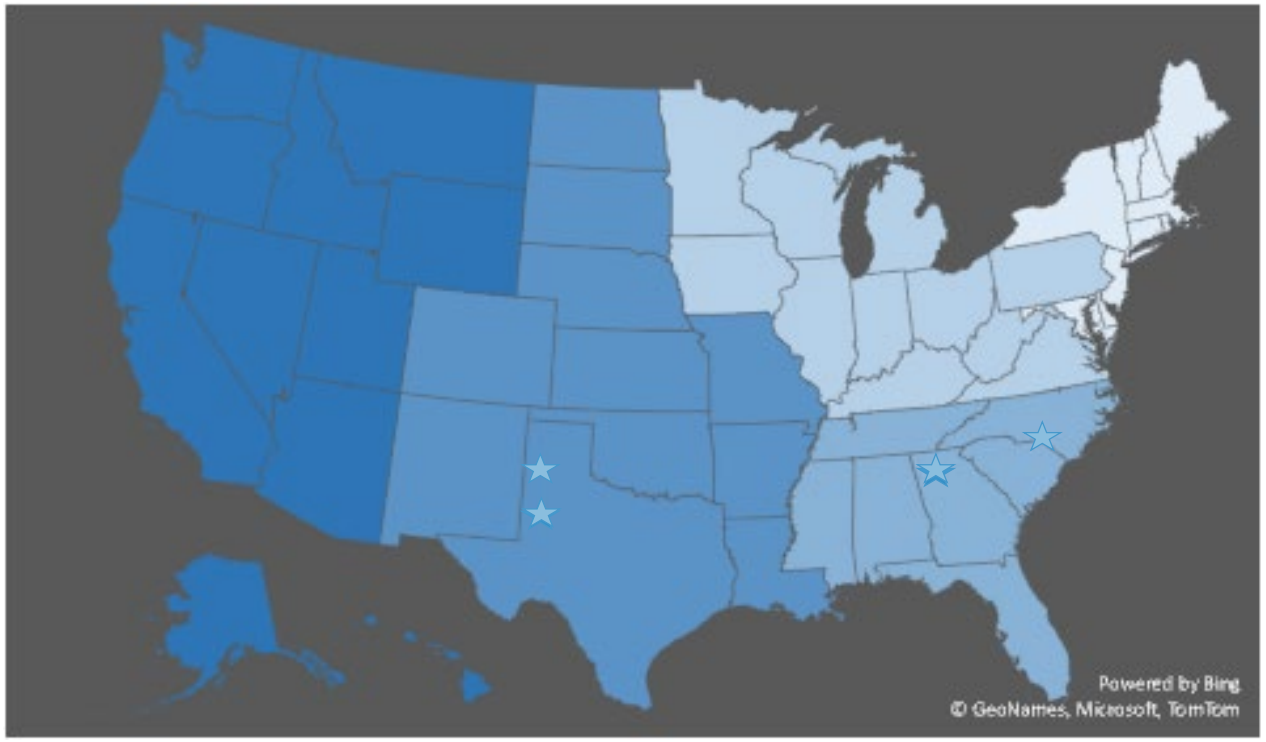
Sarah Richards, PharmD, CSP currently resides in Pittsburgh, Pennsylvania and serves as the Director of Clinical Programs for Maxor Specialty Pharmacy. Having spent 8 years as a pharmacy manager for Walgreens retail, Sarah transitioned to specialty pharmacy in 2013, where she held roles in specialty pharmacy operations as well as corporate strategy and innovation at AllianceRx Walgreens Prime. Sarah accepted a position with Maxor in 2019, and joined the specialty leadership team in February of this year. Her motto is, "Always have a passion for positive change", and hopes to bring that to life in the world of patient care and customer service models at Maxor.

AGENDA

- Review the current specialty drug and pipeline landscape
- Highlight key pipeline and market trends
- Discuss impact to business drivers from a payer and specialty pharmacy perspective
- Demonstrate how pipeline drives strategy and innovation

NATIONAL REACH AND OPERATIONAL REDUNDANCY

4 Specialty Pharmacy Locations on a **Shared Platform**



Shading represents Case Manager territories

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WHAT IS SPECIALTY?

There are many ways a drug can be considered a **specialty drug** by an organization. Specialty drugs are not defined by one standard list of criteria.

The Clinical team at Maxor Specialty takes any one of the following into consideration when determining if a drug qualifies as a **specialty drug**…

Disease State

Storage and Handling

Cost

Pharmacy Access

CURRENT SPECIALTY DRUG LANDSCAPE

Specialty % of Plan Cost

Traditional

$59.70
Average Plan Cost per Rx

Specialty

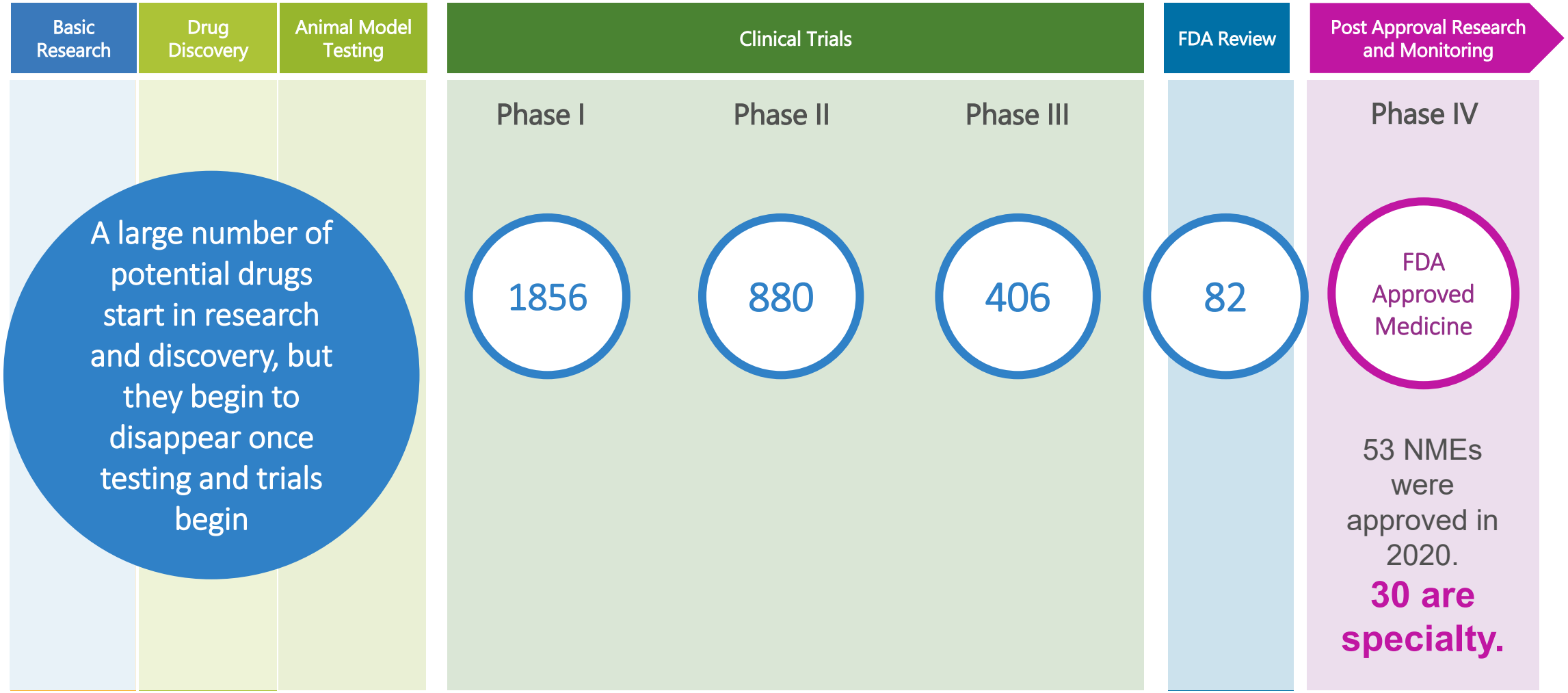
$4,735
Average Plan Cost per Rx

1.4% of utilizers drive **53%** of overall spend

By the mid-1990s, there were fewer than 30 specialty drugs on the market vs **over 900 today**

DRUGS IN CLINICAL DEVELOPMENT

Lead indication only



KEY SPECIALTY PIPELINE AND MARKET TRENDS

- Continued drug development in the Orphan/Rare disease space
- Development of Disease-modifying, or Curative Infusion Therapies
- Increasing number of Specialty Generics and Biosimilars

Are these trends Good, Bad or Neutral?

THE ELUSIVENESS OF SPECIALTY DRUGS

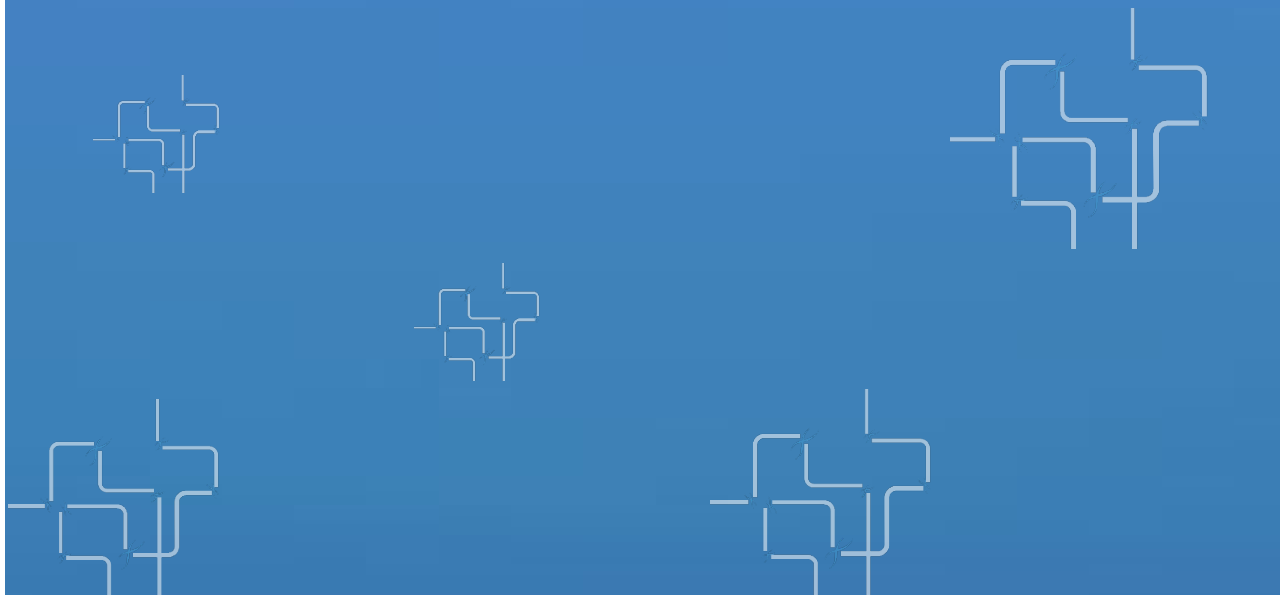
From a business perspective

Payers

- What pipeline drugs will be the most disruptive to spend?
- What pipeline drugs will allow for strategy to decrease or off-set drug spend?
    - How to avoid increasing premiums?
    - How to show value from high-cost therapies?

Specialty Pharmacies

- What pipeline drugs and relationships will drive revenue?
- What pipeline drugs will decrease market share of revenue-generating products?



EVALUATING THE DRUG PIPELINE

Where to start

Industry experts are valued partners for downstream users!

Research

Subscription services: BioMedTracker, Datamonitor, IPD Analytics

Pharma relationships

Public press releases and analyst commentary

Evaluate key drug-specific metrics

Will this drug be specialty?

Who is the target audience? Perspective is important!

What is the probability that this drug will come to market within the specified timeframe? (*confidence of approval*)

Published pipeline reports

Information is volatile and subject to change

"**You get what you give**." Can be very valuable if you know how to use them for your business

WHAT'S NEXT

How to anticipate potential utilization and/or shift in drug mix

Clinical Expertise

Understand the disease state, current treatment landscape, and market competitors

Anticipate cost

Is it likely that this drug is open, or limited distribution?

+

Analysts/Tech Support

Analyze applicable inclusion/exclusion criteria against historical claims data or dispense data

+

YOU!

How do you strategize for your business based on this information?

Bottom line

Good, Bad or Neutral is at the drug level, and may be different depending on your business unit.

KEY TRENDS

Rare/Orphan Disease and Infusion Therapies

By definition, affects a very small patient population
- A disease defined as rare when it affects fewer than 1 in 2,000 people

Ultra-high cost therapies to treat rare disease
- On average, costs about $150,000 per patient per year
- First gene therapy approved, Luxturna, cost $425,000 per eye

In the pipeline
- Epidermolysis Bulosa, Myathenia Gravis, Cystic Fibrosis, Sickle Cell Anemia, Hemophilia

Orphan/rare drugs typically prefer limited- or exclusive- specialty pharmacy network agreements

Infusion therapies (non-self administered) introduce an added layer of consideration for the business
- Consider impact to pharmacy vs medical drug spend

Expected to account for 22% of all prescription drug sales by 2024

RARE/ORPHAN DISEASE THERAPIES

Hemophilia

Industry experts will tell you to pay attention to these drugs…

Roctavian (valrox)

- Viral gene therapy by BioMarin
- Infusion therapy for the prevention of bleeding episodes in hemophilia A
- Est. approval date: H2 2022

Medical Need	• Potential first-to-market gene tx for hemophilia • Administered as a single IV dose • Curative alternative	Will displace standard of care
Efficacy	• Almost entirely eliminates need for factor VIII infusions • Patients can reach therapeutic levels within 2 weeks • Durable, long-term response shown through year 3	Curative
Safety	• Favorable safety profile • No participants developed inhibitors to factor VIII • No participants developed thrombotic events	No major side effects
Target Patient Population	• Hemophilia A is diagnosed 1 in 5,000 male birth • Currently about 20,000 individuals in the US	Small (orphan, rare disease)
Cost	• Current gene therapies upwards of $1-2 mill • May demonstrate lower overall treatment costs compared to prophylactic factor VIII	Anticipate significant impact

ValRox: GOOD, BAD OR NEUTRAL FOR YOUR BUSINESS?

Payers

How likely are you to have a patient on this drug?

- Diagnosis code(s)
  - Hemophilia
- Evaluate utilization of market competitors
  - Claims for replacement clotting factors (prophylactic therapies)
- Including, but not limited to: Advate, Alphanate, Eloctate, Humate-P, Jivi, Kovaltry, Nuwig, Hemlibra
- Demographics
  - Age over 18 (per clinical trials)
  - Utilizers with ER visits, hospital stays

Specialty Pharmacy

Will this drug be limited- or open- access?

- Manufacturer product portfolio may provide clues
- Limited distribution, via specialty pharmacy channel:
  - Palynziq, Brineura, Vimizim, Kuvan, Naglazyme, Aldurazyme, Firdapse

Can we support this drug in Specialty Pharmacy Operations?

- What storage and handling requirements?
- What additional services, or supplies, are needed?
- Does the manufacturer require enhanced reporting or dedicated resources?

Both

How will drug mix and spend shift?

- Evaluate utilization of market competitors
- Including, but not limited to: Advate, Alphanate, Eloctate, Humate-P, Jivi, Kovaltry, Nuwig, Hemlibra
- Consider shift in pharmacy vs medical benefit

CLINICAL PIPELINE SPOTLIGHT

Achondroplasia

Vosoritide [BioMarin]

- Granted Orphan designation
- If approved, will likely be the first-to-market treatment for children with achondroplasia, a form of short-limbed dwarfism
- Given once-daily via subq injection
- Potential to change the standard of care, and significantly increase drug spend for this patient population
- Regulatory decision anticipated November 20, 2021

Diabetes

Tirzepatide [Eli Lilly]

- Peptide that is a GLP-1/GIP co-agonist
- Currently in Phase III trials for both treatment of T2DM and Obesity
- Given as a weekly subcutaneous injection
- Would be a new MOA combo in the T2DM space
  - Compete against existing GLP-1 agonists
- Drug could be targeted toward higher risk patients as it may have more A1C efficacy than GLP-1 alone and greater weight loss

Epidermolysis Bullosa

Filsuvez [Amryt Pharma]

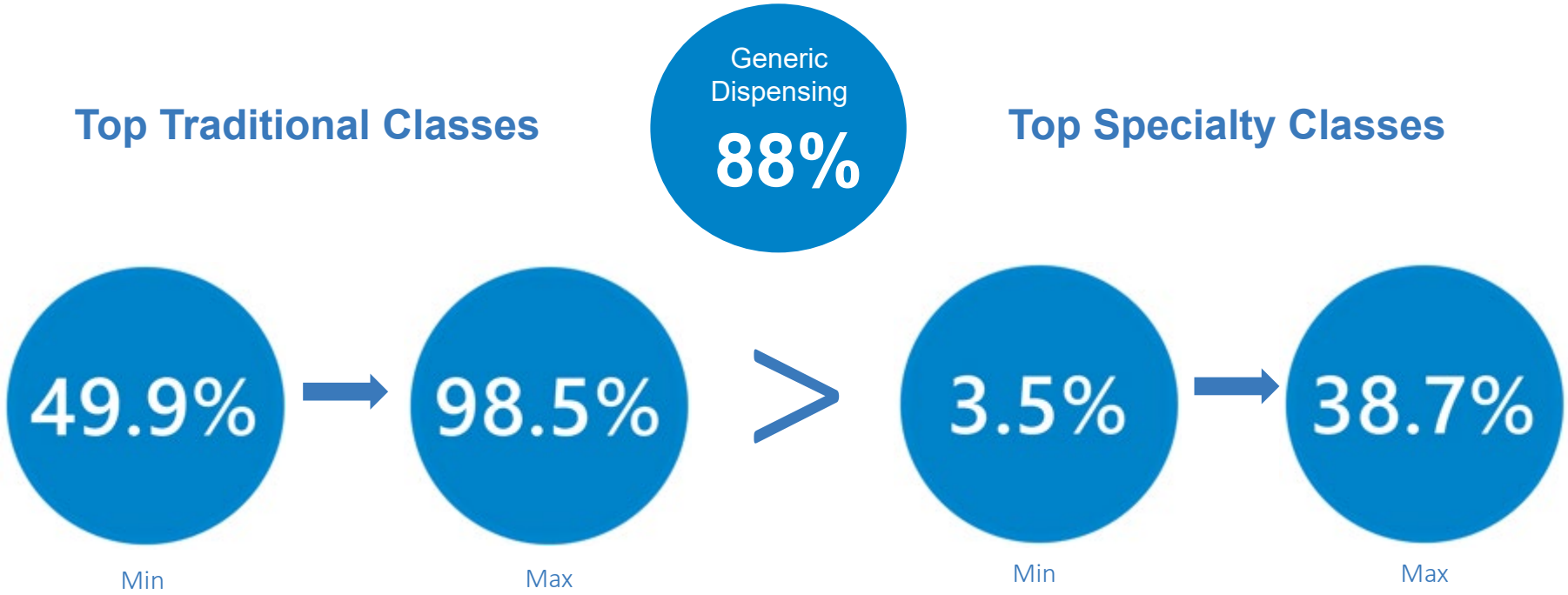
- Granted Fast Track, Orphan and Rare Disease designations
- Potential to be first-to-market, but may face near-term competition from 3 late-phase gene therapies: FCX-007, beremagene geperpavec, and EB-101
- Topical route of administration
- Potential to address a severe unmet medical need, and change the standard of care
- Regulatory decision anticipated November 30, 2021

Covid-19

Molnupiravir [Merck]

- Oral nucleoside analog antiviral
  - Works to inhibit RNA virus replication
- Shows consistent efficacy across Gamma, Delta, and Mu variants
- Used in non-hospitalized, mild to moderate Covid-19
  - Would move treatment from inpatient to outpatient (medical to pharmacy spend)
- Studies show 50% decrease risk of hospitalization or death vs placebo
- Merck applied for EUA on October 11, 2021

KEY TRENDS: SPECIALTY GENERICS AND BIOSIMILARS



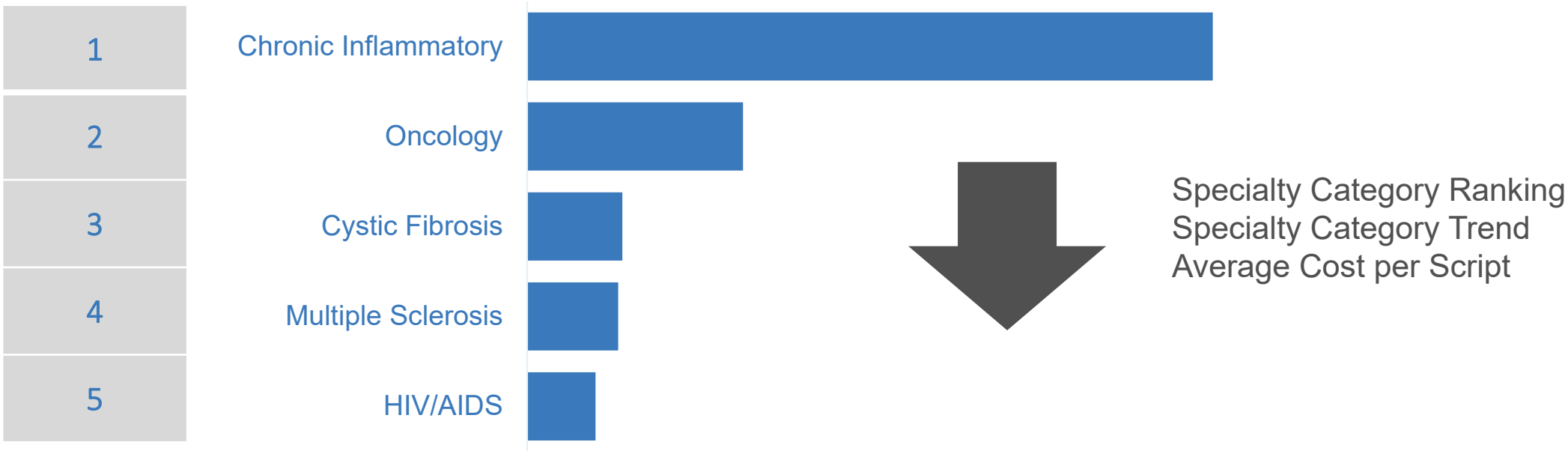
Criteria to predict or anticipate potential utilization and/or shift in drug mix

- High probability of ***launch*** *(vs approval)*
- *2+ generic Day 1 entrants will drive a more aggressive decrease in price*
- *Network access of generic vs brand*
- *Utilization of brand reference product*

GENERICS AND BIOSIMILARS: GOOD, BAD, OR NEUTRAL?

PAYER PERSPECTIVE

Specialty Category Ranking



multiple sclerosis

Launch of generic Tecfidera

- Increased YOY generic dispensing %
- Increased market competition with lower cost alternative
- Continued decrease in YOY PMPM trend

GENERICS AND BIOSIMILARS: GOOD, BAD, OR NEUTRAL?

PHARMACY PERSPECTIVE

The SP business cannot be sustained on multisource generics.

Earliest Possible Launch	Earliest Launch Probability	Day 1 Entrants	Generic Name	Brand Name	Distribution	Indication	**SP Impact**
TBD	80%	5+	Everolimus	Afinitor (10 mg)	Open	Oncology	Bad – rate deflation
03/2022	70%	1	Lenalidomide	Revlimid (5, 10, 15, 25 mg)	LTD (no access)	Oncology	Neutral – Assuming strict REMS drives LD network
07/13/2022	70%	5+	Gefitinib	Iressa	LTD (no access)	Oncology	Good – Opp'y to capture open network claims

WHAT EXCITES US MOST ABOUT THE PIPELINE

The patient perspective!

Robust drug pipeline drives **innovation**

- Much of the future pipeline is not addressable for legacy models,
- AND traditional business models will not work.

STAY TUNED! COMING IN 2022!

Part 2: Clinical Innovation and Patient Care
Part 3: Managing Specialty Drug Spend for Rare/Orphan Diseases

Improving outcomes every day

THANK YOU!

Please enter your questions in the Q/A box.

The recording of this presentation will available on maxor.com/news within 48 hours.