NDA at the FDA

Milena Lolic, MD, MS
Professional Affairs and Stakeholder Engagement
Agenda

• Before NDA: Brief overview of the drug development
• NDA at FDA: terminology and timelines
• NDA at FDA: review conduct
• Post NDA review
  • approval data
  • public information
Drug Development

https://www.youtube.com/watch?v=JVNDgfCT1pg
Timeline of Drug Development

- **Pre-clinical**
  - 3-6 years

- **Phase 1**
  - 6-7 years

- **Phase 2**

- **Phase 3**
  - 1 year

- **NDA Review**

- **Phase 4**
  - >>> years

- **pre-IND**

- **IND**

- **NDA**

- **post-approval**
NDA at FDA
Designations and Reviews

• Fast Track*
• Orphan Drug
• Breakthrough*

• Standard
• Priority*
• Rolling

Accelerated Approval*

* types of expedited programs
NDA Review Timeline
Agenda

• Before NDA: Brief overview of the drug development

• NDA at FDA: terminology and timelines

• NDA at FDA: review conduct

• Post NDA review
  • approval data
  • public information
NDA Review

Clinical

Labeling

Toxicology

Pharmacology

Chemistry

Statistics

Consults: PRO, OC, QT, DRISK, DMEPA, OPDP, PeRC, PREA, CDRH
NDA Review
Benefit-Risk Framework
NDA Review Decision
Approval

- drug name
- labeling
- promotional material
- manufacturing facilities
Agenda

• Brief overview of the drug development

• NDA at FDA: terminology and timelines

• NDA at FDA: review conduct

• NDA post FDA review:
  • more data
  • approval data
  • public review information
Post NDA Review

- FDA asks for more data
- Company expends development program
- Company/FDA follow drug safety
NDA/BLA Approval Data

CDER approvals database
Overall Median Time to Approval

- 2014: 8.1 months
- 2015: 10.9 months
- 2016: 7.8 months
Global Drug Approvals
New Active Substances - First Launches by Region 2001 – 2015

NDA post-APPROVAL

Public review information

- Press release
- FDA reviews and Prescribing Information (Drugs@FDA)
- Drug Trial Snapshots
Accessing FDA Reviews
Accessing FDA Reviews
Drug Trials Snapshots

WHAT IS THE PURPOSE OF DRUG TRIALS SNAPSHOTs?

Drug Trials Snapshots provide consumers with information about who participated in clinical trials that supported the FDA approval of new drugs. The information provided in these Snapshots also highlights whether there were any differences in the benefits and side effects among sex, race and age groups. Drug Trials Snapshots is part of an overall FDA effort to make demographic data more available and transparent.

HOW TO USE SNAPSHOTs:

Each Snapshot contains information about the drug in a question and answer format. At the end of each section of the Snapshot, there is a shaded bar with the words “MORE INFO”. Click the “MORE INFO” bar for more technical and detailed content. At the bottom of each Snapshot, there is a link to the drug’s Package Insert as well as the medical review.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Active Ingredient</th>
<th>Date of FDA Approval</th>
<th>What is it Approved For</th>
<th>Package Insert</th>
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<tbody>
<tr>
<td>ADDYI</td>
<td>fibanserin</td>
<td>August 18, 2015</td>
<td>Treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women</td>
<td>Addyi</td>
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<td>ADLYXIN</td>
<td>lixisenatide</td>
<td>July 27, 2016</td>
<td>Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise</td>
<td>Adlyxin</td>
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<td>ALECENSA</td>
<td>aleclacinib</td>
<td>December 11, 2015</td>
<td>For the treatment of metastatic non-small cell lung cancer</td>
<td>Alecensa</td>
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<td>ANTHIM</td>
<td>oblimexinab</td>
<td>March 18, 2010</td>
<td>For the treatment of inhalational anthrax</td>
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<td>ARISTADA</td>
<td>aripiprazole laurixil</td>
<td>October 5, 2015</td>
<td>Treatment of schizophrenia</td>
<td>Aristada</td>
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<td>AVYCAZ</td>
<td>ceftazidine-avibactam</td>
<td>February 25, 2015</td>
<td>Treatment of complicated intra-abdominal infection (abbreviated as cIAI)</td>
<td>Avycaz</td>
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<tr>
<td>AVYCAZ</td>
<td>ceftazidine-avibactam</td>
<td>February 25, 2015</td>
<td>Treatment of complicated urinary tract infection (abbreviated as cUTI)</td>
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<tr>
<td>AXUMIN</td>
<td>flucelovine F 18</td>
<td>May 27, 2016</td>
<td>Detection of prostate cancer recurrence</td>
<td>Axumin</td>
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<td>BRIDION</td>
<td>sugammadex</td>
<td>December 15, 2015</td>
<td>For the reversal of the effects of certain neuromuscular blocking agents</td>
<td>Bridion</td>
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<tr>
<td>BRIVIACT</td>
<td>briveracetam</td>
<td>February 18, 2016</td>
<td>Treatment of partial-onset seizures</td>
<td>Briviact</td>
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<td>cholic acid</td>
<td>March 17, 2015</td>
<td>For treatment of bile acid synthesis disorders due to single enzyme defects</td>
<td>Cholbam</td>
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<tr>
<td>CHOLBAM</td>
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<td>March 17, 2015</td>
<td>For treatment of peroxisomal disorders, including Zellweger spectrum disorders</td>
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<td>CINQUAIR</td>
<td>resizumab</td>
<td>March 23, 2015</td>
<td>For the treatment of a specific type of severe asthma (called eosinophilic phenotype asthma)</td>
<td>Cinquair</td>
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<td>CORLANOR</td>
<td>ivabradine</td>
<td>April 15, 2015</td>
<td>To reduce hospitalization from worsening heart failure</td>
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<td>COSENTYX</td>
<td>secukinumab</td>
<td>January 21, 2015</td>
<td>Treatment of moderate to severe plaque psoriasis in adults who do not respond fully to conventional therapy</td>
<td>Cosentyx</td>
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Who Participated in the Clinical Trials?

Race:
- White (10,437 patients)
- Black or African American (308 patients)
- Asian (350 patients)
- Native Hawaiian or Pacific Islander (29 patients)
- American Indian or Alaska Native (11 patients)
- Unknown (10 patients)

Age:
- 17-64 years (5,794 patients)
- 65-74 years (3,318 patients)
- >=75 (2,033 patients)

Sex:
- Male (8,024 patients)
- Female (3,121 patients)
Content of a Snapshot

• Information about who participated in the clinical trials
  and
• Information about
  – trial design
  – overall drug efficacy and safety
  – differences in efficacy and safety among sex, race, and age subgroups
# Public Info Comparison

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<th></th>
<th>Reviews</th>
<th>PI</th>
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<td>Demographics in drug development program</td>
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<td>Reasons for specific subgroup representation</td>
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<td>Consumer friendly information</td>
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<td>✔</td>
<td>✔✔✔</td>
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