The Specialty Landscape of the Future

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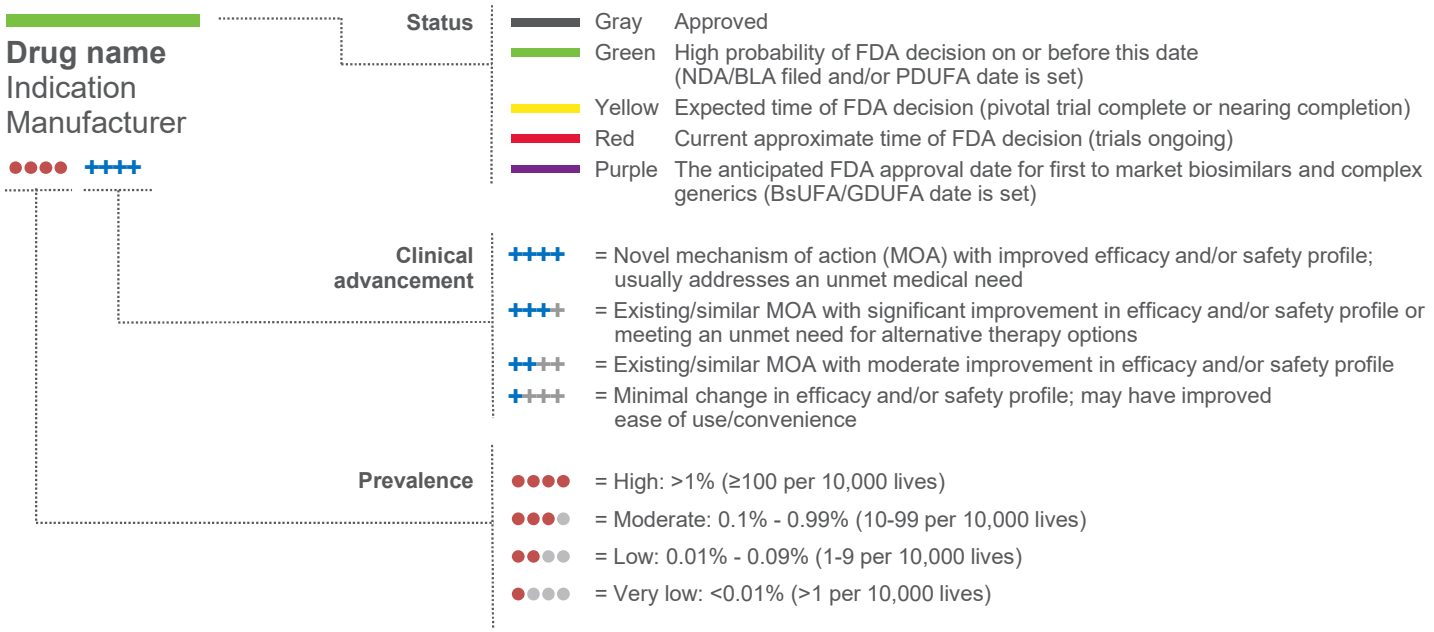
Fun Facts Quiz

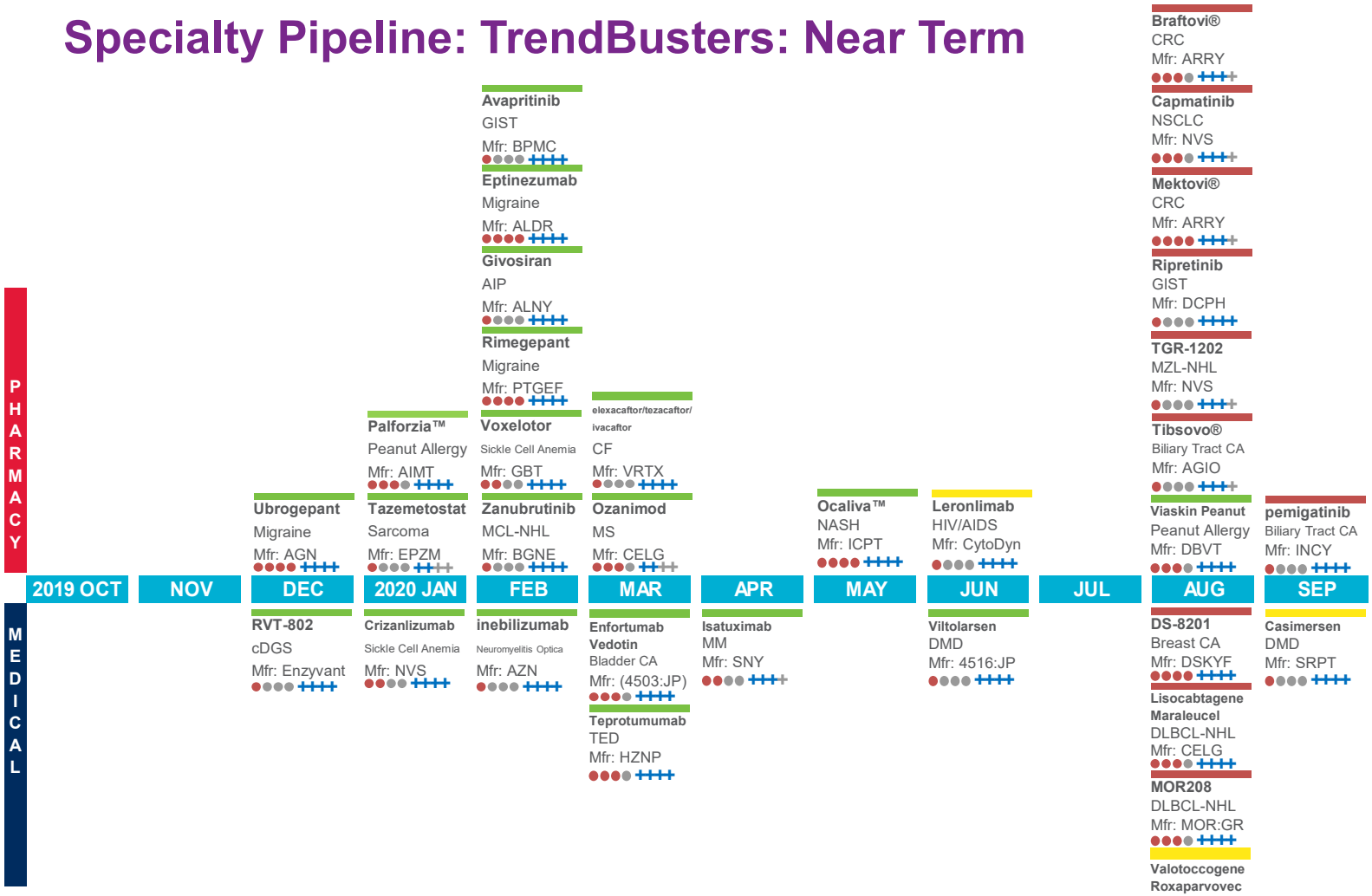
1. Since 2000, the number of specialty drug approvals has increased by : 250%, 430%, 580%, 600%
2. X% of all specialty drugs have been approved since 2014: 15%, 25%, 30%, 35%
3. Specialty drug spend is now X% of total drug spend: 30%, 40%, 50%, 60%
4. Specialty drug spend is predicted to reach X% by 2021?

Specialty Pipeline Key



Specialty Pipeline: TrendBusters

Specialty Pipeline: TrendBusters: Near Term



*May be eligible for pharmacy benefit coverage depending on FDA approval language

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NASH Nonalcoholic Steatohepatitis

NAFLD Nonalcoholic Fatty Liver Disease

NASH

- Affects 6-16 Million Americans with an additional 3 Million diagnosed each year.
- In the US, 34% of individuals over the age of 40 have NAFLD and 12% have NASH
- Currently third leading cause of liver transplant but expected to be leading cause by 2020
- Pathology: build up of fat in the liver leading to inflammation and damage resulting in scarring and cirrhosis
- Symptoms: in the early stage there are no symptoms, as disease progresses there is fatigue, weight loss, weakness, pain in the upper right quadrant of abdomen.
- Individuals often have Type 2 diabetes, high cholesterol and triglycerides, metabolic syndrome

Current treatment is diet and exercise along with management of comorbidities.
If approved in May, Ocaliva (currently approved to treat primary biliary cholangitis) will be the first drug with the indication to treat this disease.

Gene Modifying Therapies versus CAR-T

Gene Therapy

- Gene Therapy involves the transferring of genetic material into a patient.
- The genetic material changes how protein(s) is/are produced by targeted cells.
- The result is the introduction, removal, or change in the content of a person's genetic code to treat or cure the disease.
- Carriers/vectors transport the genetic material to the targeted cells.

Cell Therapy

- Cell therapy is the transfer of intact, live cells into a patient to help lessen or cure a disease. The cells may originate from the patient (autologous cells) or a donor (allogeneic cells).
- The type of cells administered depends on the treatment (e.g., pluripotent, multipotent, and primary).
- ChimericAntigenReceptor (CAR)T-cell therapy modifies a patient's own immune cells (T-cells), which attach to antigens on the surface of cancer cells

What is the risk?

- Gene Therapies carry significant risk as the population eligible for treatment is unknown
  - -High cost from several hundred thousand dollars to several million
  - -Cost is often based on a one time treatment rather than spread over a lifetime
  - -Current coverage and plan design may need modification
  - -Total cost of care of disease weighed against treatment

- How does a plan manage a very small number of individuals whose treatment is high cost?

- Treatment only at Centers of Excellence? P4P with manufacturers? Continued efficacy?

Examples:

First CAR-T therapy 2010 – prostate cancer, $63,000/dose
2 CAR-T therapies in 2017 – leukemia, lymphoma - $570,000 and $450,000
First Gene therapy 2017 – retinitis pigmentosa - $500,000 per eye
1 Gene therapy 2019 – Type 1 spinal muscular atrophy - $2.1 M