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Catalyst Roundup:

A Review of Select Catalysts from Last Quarter's Outlook Report

Biomedtracker's quarterly Outlook Reports detail important upcoming catalysts not to miss. Here's a look at the outcome of two catalysts featured in the Q2 2024 Outlook Report.

DRUG:
mRESVIA for Respiratory Syncytial Virus (RSV) Prevention

Moderna, Inc. (MRNA)

CATALYST OCCURRED:
PDUFA for BLA - First Review

May 31, 2024

FDA DECISION

- The US Food and Drug Administration (FDA) has approved mRESVIA (mRNA-1345), an mRNA respiratory syncytial virus (RSV) vaccine, to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection.

- The FDA's approval of mRESVIA is based on data from the Phase III clinical trial ConquerRSV, a global study conducted in approximately 37,000 adults ages 60 years or older in 22 countries. The primary analysis with 3.7 months of median follow-up found a vaccine efficacy against RSV lower respiratory tract disease (LRTD) of 83.7% (95.88% CI 66.0%, 92.2%). A follow-up analysis of the primary endpoint was performed during FDA review, including cases that started before the primary analysis cut-off date. The results were consistent with the primary analysis [VE 78.7% (CI 62.9%, 87.8%)] and were included in the US package insert.

Moderna: "The FDA approval of our second product, mRESVIA, builds on the strength and versatility of our mRNA platform. This approval is also the first time an mRNA vaccine has been approved for a disease other than COVID-19. With mRESVIA, we continue to deliver for patients by addressing global public health threats related to infectious diseases."

MDNA: 5-DAY STOCK PERFORMANCE

BIOMEDTRACKER ANALYSES

Change to Likelihood of Approval (LOA): +1%

LOA before approval	LOA after approval
99% (6% Above Avg.)	100% (Same as Avg.)

NEXT STEPS

European Approval Decision
Sept. 9, 2024

DRUG:
CAPVAXIVE for Pneumococcal Vaccines (Antibacterial)
Merck & Co., Inc. (MRK)

CATALYST OCCURRED:
PDUFA for BLA - First Review

June 17, 2024

FDA DECISION

- The US Food and Drug Administration (FDA) has approved CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B in individuals 18 years of age and older; and active immunization for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B in individuals 18 years of age and older.

- The approval follows the FDA's Priority Review of Merck's application. This indication for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Merck: "Today's approval is a testament to our population-specific strategy behind CAPVAXIVE, which demonstrated robust immunogenicity in a range of adult populations and is driven by a deep understanding of pneumococcal disease. We are proud to provide CAPVAXIVE as a new option specifically designed to help protect against the majority of invasive pneumococcal disease-causing serotypes in adults."

MRK: 5-DAY STOCK PERFORMANCE

BIOMEDTRACKER ANALYSES

Change to Likelihood of Approval (LOA): +1%

LOA before decision	LOA after decision
99% (6% Above Avg.)	100% (Same as Avg.)

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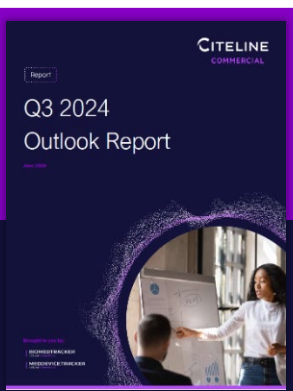

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