

gamida Cell

FDA approves gamida Cell's OMISIRGE as the first cell therapy for severe aplastic anemia showing rapid blood count recovery

( FDA, Approval )

elethon

Fondazione Telethon ETS announces FDA approval of WASKYRA, a gene therapy for the treatment of Wiskott-Aldrich syndrome in eligible patients

( FDA, Approval )

amneal

Amneal expands its injectables portfolio with FDA approval for EPINEPHRINE injection in single- and multi-dose vials for US hospitals

( FDA, Approval )

INNOVIVA™

Innoviva Specialty Therapeutics announces FDA approval of NUZOLVENCE, a single-dose, oral antibiotic, for the treatment of uncomplicated urogenital gonorrhea in adults and adolescents

( FDA, Approval )





GSK gains FDA approval of BLUJEPA, an oral antibiotic, for the treatment of uncomplicated urogenital gonorrhoea in adults and adolescents with limited or no alternative options, offering the first new antibiotic class for gonorrhoea

*( FDA, Approval )*



FDA approves UPLIZNA for the treatment of adults with generalized myasthenia gravis who are anti-acetylcholine receptor and anti-muscle specific tyrosine kinase antibody positive

*( FDA, Approval )*



FDA approves J&J's AKEEGA plus prednisone as the first precision therapy for BRCA2-mutated metastatic castration-sensitive prostate cancer

*( FDA, Approval )*



EMA recommends conditional marketing authorization for Immunity Bio's ANKTIVA to treat BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ

*( EMA, Marketing Authorization )*



GSK

GSK's DEPEMOKIMAB gets a positive CHMP opinion for severe asthma with type 2 inflammation and chronic rhinosinusitis with nasal polyps

*( CHMP, Positive Opinion )*

百奥泰  
BIO-THERA

Biosimilar GOTENFIA, from Stada and Bio-Thera, receives a positive CHMP opinion, recommending approval for several inflammatory autoimmune diseases

*( CHMP, Positive Opinion )*

MERCK

Merck receives positive CHMP opinion for the expanded use of WINREVAIR in combination with other therapies for adults with pulmonary arterial hypertension (WHO FC II-IV)

*( CHMP, Positive Opinion )*

GSK

GSK's NUCALA receives positive CHMP opinion as an add-on treatment for uncontrolled COPD in adults with raised blood eosinophils

*( CHMP, Positive Opinion )*



*( CHMP, Positive Opinion )*



Sobi receives a positive CHMP opinion for ASPAVELI for the treatment of C3G and primary IC-MPGN (rare kidney diseases) in adult and adolescent patients

*( FDA, Priority Review )*



FDA grants priority review to BMS's sBLA for OPDIVO in combination with chemotherapy for previously untreated advanced classical Hodgkin lymphoma

*( FDA, Orphan Drug )*



GSK's antibody drug conjugate, GSK'227, receives Orphan Drug designation for small cell lung cancer from the FDA

*( Acquisition )*



Mirum Pharmaceuticals enters into a definitive agreement to acquire Bluejay Therapeutics, expanding its rare disease portfolio with the addition of brelovitug for chronic hepatitis delta virus





*( Acquisition )*  
Sobi to acquire ArthroSi Therapeutics, strengthening its pipeline with pozdeutinurad, a potential gout treatment



*( Collaboration )*  
Pfizer obtains exclusive global rights from YaoPharma to develop and commercialize YP05002, an oral GLP-1 agonist for obesity, in a deal worth up to \$2.085 billion

