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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **OCTOBER 2022**

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 11/9/2022

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NEWS

- No drug safety alert published by the FDA in October.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
IMJUDO™ (TREMELIMUMAB-ACTL) INJECTION	ASTRAZENECA AB	10/21/2022

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Imjudo™ is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody indicated in combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).

DOSAGE AND ADMINISTRATION
Weight-based dosing:

- Weight 30 kg and more: 300 mg as a single dose in combination with durvalumab 1,500 mg at Cycle 1/Day 1, followed by durvalumab as a single agent every 4 weeks
- Weight less than 30 kg: 4 mg/kg as a single dose in combination with durvalumab 20 mg/kg at Cycle 1/Day 1, followed by durvalumab as a single agent every 4 weeks

Administer Imjudo™ as an intravenous infusion over 60 minutes after dilution

DOSAGE FORMS AND STRENGTHS

- Injection: 25 mg/1.25 mL (20 mg/mL) solution in a single-dose vial
- Injection: 300 mg/15 mL (20 mg/mL) solution in a single-dose vial

SAFETY PROFILE

CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS

- Immune-Mediated Adverse Reactions: Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis with renal dysfunction and immune-mediated pancreatitis.
  - Monitor for early identification and management. Evaluate liver enzymes, creatinine, adrenocorticotropic hormone level and thyroid function at baseline and before each dose.
  - Withhold or permanently discontinue based on severity and type of reaction.
- Infusion-Related Reactions: Interrupt, slow the rate of infusion, or permanently discontinue treatment based on the severity of the reaction.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.

ADVERSE REACTIONS

- Most common adverse reactions (≥ 20%) of patients with uHCC are rash, diarrhea, fatigue, pruritus, musculoskeletal pain, and abdominal pain. Most common laboratory abnormalities (≥ 40%) of patients with uHCC are AST increased, ALT increased, hemoglobin decreased, sodium decreased, bilirubin increased, alkaline phosphatase increased, and lymphocytes decreased.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on findings from animal studies and its mechanism of action, Imjudo™ can cause fetal harm when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with Imjudo™ and for 3 months after the last dose.
- Females and Males of Reproductive Potential: Verify pregnancy status of females of reproductive potential prior to initiating treatment with Imjudo™. Advise females of reproductive potential to use effective contraception during treatment with Imjudo™ and for 3 months after the last dose.
- Pediatric Use: The safety and effectiveness of tremelimumab-actl have not been established in pediatric patients.

Orphan status: Yes

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TECVAYLI™ (TECLISTAMAB) INJECTION	JANSSEN BIOTECH, INC.	10/25/2022

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Tecvayli™ is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

DOSAGE AND ADMINISTRATION
The recommended dosage is step-up doses of 0.06mg/kg and 0.3mg/kg followed by 1.5mg/kg once weekly until disease progression or unacceptable toxicity. Administer subcutaneously. Due to the risk of cytokine release syndrome and neurologic toxicity, patients should be hospitalized for 48 hours after administration of all doses within the Tecvayli™ step-up dosing schedule.

DOSAGE FORMS AND STRENGTHS
- Injection: 30 mg/3 mL clear to slightly opalescent, colorless to light yellow solution in a single-dose vial
- Injection: 153 mg/1.7 mL clear to slightly opalescent, colorless to light yellow solution in a single-dose vial

SAFETY PROFILE

CONTRAINDICATIONS
- None.

WARNINGS AND PRECAUTIONS
- **BLACK BOX WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY INCLUDING IMMUNE EFFECTOR CELL-ASOCIATED NEUROTOXICITY SYNDROME**
  - Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving Tecvayli™. Initiate treatment with Tecvayli™ step-up dosing schedule to reduce risk of CRS. Withhold Tecvayli™ until CRS resolves or permanently discontinue based on severity.
  - Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur with Tecvayli™. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold Tecvayli™ until neurologic toxicity resolves or permanently discontinue based on severity.
  - Because of the risk of CRS and neurologic toxicity, including ICANS, Tecvayli™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Tecvayli™ REMS.

WARNING AND PRECAUTIONS (CONT.)
- **REMS**
  - Tecvayli™ is available only through a restricted program under a REMS called the Tecvayli™ REMS because of the risks of CRS and neurologic toxicity, including ICANS.
  - Notable requirements of the Tecvayli™ REMS include the following:
    - Prescribers must be certified with the program by enrolling and completing training.
    - Prescribers must counsel patients receiving Tecvayli™ about the risk of CRS and neurologic toxicity, including ICANS, and provide patients with Patient Wallet Card.
    - Pharmacies and healthcare settings that dispense Tecvayli™ must be certified with the Tecvayli™ REMS program and must verify prescribers are certified through the Tecvayli™ REMS program.
    - Wholesalers and distributers must only distribute Tecvayli™ to certified pharmacies or healthcare settings.

Orphan status: Yes

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TECVAYLI™ (TECLISTAMAB) INJECTION	JANSSEN BIOTECH, INC.	10/25/2022

THERAPEUTIC CLASS
Antineoplastics

FDA-APPROVED INDICATION(S)
Tecvayli™ is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

DOSAGE AND ADMINISTRATION
The recommended dosage is step-up doses of 0.06mg/kg and 0.3mg/kg followed by 1.5mg/kg once weekly until disease progression or unacceptable toxicity. Administer subcutaneously. Due to the risk of cytokine release syndrome and neurologic toxicity, patients should be hospitalized for 48 hours after administration of all doses within the Tecvayli™ step-up dosing schedule.

DOSAGE FORMS AND STRENGTHS
- Injection: 30 mg/3 mL clear to slightly opalescent, colorless to light yellow solution in a single-dose vial
- Injection: 153 mg/1.7 mL clear to slightly opalescent, colorless to light yellow solution in a single-dose vial

SAFETY PROFILE

WARNINGS AND PRECAUTIONS (CONT.)
- Hepatotoxicity: Tecvayli™ can cause hepatotoxicity, including fatalities. Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold Tecvayli™ or consider permanent discontinuation of Tecvayli™ based on severity.
- Infections: Tecvayli™ can cause severe, life-threatening, or fatal infections. Monitor patients for signs and symptoms of infection prior to and during treatment with Tecvayli™ and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold Tecvayli™ or consider permanent discontinuation of Tecvayli™ based on severity. Monitor immunoglobulin levels during treatment with Tecvayli™ and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.
- Neutropenia: Tecvayli™ can cause neutropenia and febrile neutropenia. Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold Tecvayli™ based on severity.
- Hypersensitivity and Other Administration Reactions: Tecvayli™ can cause both systemic administration-related reactions and local injection-site reactions. Withhold Tecvayli™ or consider permanent discontinuation of Tecvayli™ based on severity.

WARNINGS AND PRECAUTIONS (CONT.)
- Embryo-Fetal Toxicity: Based on its mechanism of action, Tecvayli™ may cause fetal harm when administered to a pregnant woman.

ADVERSE REACTIONS
- The most common adverse reactions (≥20%) are pyrexia, cytokine release syndrome, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥20%) are decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on the mechanism of action, Tecvayli™ may cause fetal harm when administered to a pregnant woman.
- Lactation: Because of the potential for serious adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with Tecvayli™ and for 5 months after the last dose.
- Females and Males of Reproductive Potential: Verify pregnancy status of females of reproductive potential prior to initiating Tecvayli™. Advise females of reproductive potential to use effective contraception during treatment and for 5 months after the last dose of Tecvayli™.

Orphan status: Yes

NEW BIOSIMILAR PRODUCTS

- No biosimilar product was approved by the FDA in October.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	ADDITIONAL INFORMATION
FUROSCIX™ (FUROSEMIDE) FOR SUBCUTANEOUS USE / SCPHARMACEUTICALS, INC.	Diuretics	Treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure	10/7/2022	Furoscix™ is a pH-neutral formulation of furosemide designed for subcutaneous administration via an on-body infusor for self-administration. It demonstrated 99.6% bioavailability and produced similar effect as intravenous furosemide. Orphan: No
MENVEO™ (MENINGOCOCCAL [GROUPS A, C, Y, AND W-135] OLIGOSACCHARIDE DIPHTHERIA CRM197 CONJUGATE VACCINE) SOLUTION FOR INJECTION / GSK VACCINES	Vaccines	For active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A,C, Y, and W-135 in individuals 10 through 55 years of age	10/14/2022	The FDA has approved a new presentation of Menveo™ that removes the need for reconstitution before use (single-vial presentation). This formulation is approved for individuals between the ages of 10 to 55 years of age, which differs from the other presentation that is indicated for individuals 2 through 55 years of age. Orphan: No

NEW FIRST-TIME GENERIC APPROVALS

- No first-time generic approved by the FDA in October.

NEW
FDA-APPROVED INDICATIONS
FOR EXISTING DRUGS

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NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
OXLUMO™ (LUMASIRAN) INJECTION / ALNYLAM PHARMACEUTICALS, INC.	Genitourinary agents	Treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients	Treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients	10/6/2022
LYUMJEV™ (INSULIN LISPRO-AABC) INJECTION / ELI LILLY AND CO.	Antidiabetics	To improve glycemic control in adult patients with diabetes mellitus	To improve glycemic control in adult and pediatric patients with diabetes mellitus	10/14/2022
VEMLIDY™ (TENOFOVIR ALAFENAMIDE) TABLETS / GILEAD SCIENCES, INC.	Antivirals	Treatment of chronic hepatitis B virus infection in adults with compensated liver disease	Treatment of chronic hepatitis B virus infection in adults and pediatric patients 12 years of age and older with compensated liver disease	10/17/2022
RINVOQ™ (UPADACITINIB) EXTENDED-RELEASE TABLETS /	Analgesics – anti-inflammatory	Treatment of moderately to severely active rheumatoid arthritis, active psoriatic arthritis, moderate to severe atopic dermatitis, moderately to severely active ulcerative colitis, active ankylosing spondylitis	Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy	10/21/2022
COTELLIC™ (COBIMETINIB) TABLETS / GENENTECH INC.	Antineoplastics and adjunctive therapies	Treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib	As a single agent for the treatment of adult patients with histiocytic neoplasms	10/28/2022

PIPELINE

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PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	ADDITIONAL INFORMATION	IMPACT
CYCLASOL™ (CYCLOSPORINE) OPHTHALMIC SOLUTION / NOVALIQ	10/24/2022	Treatment for the signs and symptoms of dry eye disease (DED)	Cyclasol™ is an anti-inflammatory product that has been created by Novaliq using EyeSol®, a water-free technology. This technology increases the time on the eye from minutes to hours and enables high bioavailability of the active ingredient. The Prescription Drug User Fee Act (PDUFA) target action date set by the FDA is June 8th, 2023. NDA accepted.	Moderate
SER-109 / SERES THERAPEUTICS, INC.	10/26/2022	Prevention of recurrent *C. difficile* infection (rCDI)	SER-109 is an investigational microbiome therapeutic which is designed to remove unwanted microbes, thereby reducing the risk of pathogen transmission. The FDA has granted SER-109 Breakthrough Therapy designation and Orphan Drug designation for the prevention of rCDI. The Prescription Drug User Fee Act (PDUFA) target action date set by the FDA is April 26th, 2023. BLA accepted.	High high
EPCORITAMAB / GENMAB A/S	10/28/2022	Treatment of patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy	Epcoritamab is an investigational IgG1-bispecific antibody created using Genmab's DuoBody-CD3 technology which is designed to direct cytotoxic T cells selectively to elicit an immune response towards target cell types. BLA submitted.	High

REFERENCES

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- *Latest Generic Drug Approvals*. Drugs.com. (2022). https://www.drugs.com/generic-approvals.html.
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